

# Exhibit

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February 2, 2023

**RE: U.S.A. v. Orlandis Wells, M.D.**

This Report is being made at the request of Christopher Oram, Esq., to meet the requirements of the Federal Rules of Civil Procedure, Rule 26(2)(A) and (B), which I have been informed requires me to give a complete statement of all opinions that I will express and the basis and reasons for them; the facts or data that I considered in forming my opinions; identify any exhibits that will be used to summarize or support my opinions; a curriculum vitae setting for the my qualifications (including a list of all publications authored in the previous 10 years), a list of other cases in which, during the previous four years in which I have testified at trial or by deposition; and a statement of the compensation to be paid for my study and testimony in this case.

1. I am licensed as a medical doctor in the States of Nevada, Idaho, Colorado, Alabama, Mississippi, Texas, and Wisconsin. I do hold an inactive medical license in Washington State.
2. I have practiced pain management nearly continuously since 1995 and have over 25 years of experience managing acute and chronic pain patients with medications, including opioid medications, and other interventions as part of a multimodal pain management approach.
3. I have over 25 years of experience as a physician. During this time, I have been employed as a primary care physician, pain management specialist, urgent care physician, addiction specialist, medical school faculty physician, and most recently, medical director of Flamingo Medical Clinic, a primary care, addiction, and pain management clinic.

4. I hold a Bachelor of Science Degree in Zoology *summa cum laude* from the University of Idaho.
5. I hold a Doctor of Medicine degree from the University of Washington School of Medicine in Seattle.
6. I completed a one-year family practice/ transitional year internship at Deaconess Medical Center in Spokane, Washington.
7. I completed a three-year residency in anesthesiology at the University of Washington School of Medicine Seattle.
8. I completed a one-year fellowship in pain management at the University of Washington School of Medicine in Seattle.
9. I hold a Juris Doctor degree from the UNLV Boyd School of Law in Las Vegas and am actively licensed as an attorney in the State of Nevada.
10. My experience and education are documented in my curriculum vitae, as are recent publications and abstracts, attached hereto as **Exhibit 1**.
11. My Rate Sheet and prior testimony in the previous four years are attached hereto as **Exhibit 2**.
12. I am board-certified by the National Board of Medical Examiners. I am also board-certified in Anesthesiology by the American Board of Medical Specialties member board, the American Board of Anesthesiology.
13. I have been retained to review documents in this case and offer an expert medical opinion and that is the purpose of this Report.
14. I have reviewed the following documents and healthcare related records and bills in this matter:
  - a. Criminal Indictment of Orlandis Wells, MD
  - b. Dr. Wells' Motion to Dismiss All Counts of the Indictment

- c. Government's Response in Opposition to Motion to Dismiss all Counts of the Indictment
- d. Reply to Government's Response to Dr. Wells' Motion to Dismiss All Counts of the Indictment
- e. Complaint of Pharmacist Jung Kook to Nevada State Board of Medical Examiners
- f. Report of Jeffrey J. Muir, MD (3-pages)
- g. Report of Jeffrey J. Muir, MD (19-pages)
- h. Report of Timothy Munzing, MD
- i. File on "Patient Martin"
- j. File on Patient A
- k. File on Patient B
- l. File on Patient C
- m. File on Patient D
- n. File on Patient E
- o. File on Patient F
- p. File on Patient G
- q. File on Patient H
- r. File on Patient I
- s. File on Patient J
- t. File on Patient K
- u. File on Patient L
- v. File on Patient M
- w. File on Patient N
- x. File on Patient O
- y. Federation of State Medical Boards, Guidelines for the Chronic Use of Opioid Analgesics

### OPINIONS

- 15. The Government's implication that obstetricians/ gynecologists are not qualified to treat male patients is categorically false.**

While it is true that obstetrician/ gynecologists treat mostly women, the American College of Obstetrician Gynecologists (ACOG) has specifically denounced the idea that gynecologists cannot and should not treat men. Historically, gynecologists have been involved in the treatment of men for sexually transmitted infections, including screening men for rectal cancer. It is also my understanding that gynecologists may work at clinics where infertility workups are performed on men. Some gynecologists may work at Planned Parenthood Clinics where services are offered to men, including treatment for erectile dysfunction. Screening for prostate cancer and testicular cancer may also be performed in these clinics.

A 2013 article in the New York Times clearly articulated that The American Board of Obstetrics and Gynecology permitted their diplomates to treat men and remain in good standing with the Board. This occurred after the Board had previously attempted to limit the patient population to females. See **Exhibit 3**.

Additionally, in Nevada, there is a long history of gynecologists being involved in primary care. For example, one of Nevada's largest primary care clinics for indigents in Nevada is the Volunteers in Medicine in Southern Nevada, founded by Las Vegas gynecologist, Florence Jameson, MD. See **Exhibit 4**.

Frank Silver, MD is a gynecologist and father of the Honorable Abbi Silver, a recently retired Nevada Supreme Court Justice. For many years, Dr. Silver oversaw a primary care clinic for indigent patients on Las Vegas's northeast side. Dr. Silver continues to supervise staff at the Desert Inn Medical Clinic on Desert Inn Road.

**16. There are almost no medications used in pain management that are dosed differently by gender.**

The vast majority of medications used in pain management are dosed on a milligram per kilogram basis. There are only a few medications in all of medicine that are dosed differently based on the gender of the patient. Most of these would be sex hormones or medications that are contraindicated in pregnancy. There is no credible medical reason to conclude that an obstetrician gynecologist would be unable to treat pain in male patients.

**17. The Government's implication that obstetrician/ gynecologists are not qualified to manage pain is categorically false.**

The Government's implication that obstetricians and gynecologists are not qualified to treat acute and chronic pain is absurd. Obstetricians frequently manage the pain of all three stages of labor. Chronic pelvic pain is an extremely common presenting diagnosis for gynecologists. Gynecologists also commonly treat postoperative pain with opioids and other medications.

Importantly, the American College of Graduate Medical Education in Obstetrics and Gynecology requires that physician trainees in obstetrics and gynecology be educated on the management of pain and on how to recognize substance abuse. See Exhibit 5.

18. **The standard of care in pain management is not determined by adherence to *The Federation of State Medical Boards' (FSMB) Model Policy on the Use of Opioid Analgesics in the Treatment of Chronic Pain*.**

Numerous governmental authorities, private organizations, and practice organizations have promulgated recommendations, clinical practice guidelines, suggestions, instructions, requirements, practice parameters, and other directions to providers for the prescribing of opioids in the management of pain. There are scores of such directives. None of them alone establishes the standard of care for physicians practicing in Nevada or elsewhere.

The *Federation of State Medical Boards' (FSMB) Model Policy on the Use of Opioid Analgesics in the Treatment of Chronic Pain*, specifically and emphatically states the following:

#### **Section 2 – FOCUS OF GUIDELINES**

The focus of the Guidelines that follow is on the general overall safe and evidence-based prescribing of opioids and treatment of chronic, non-cancer pain with the specific limitation and restriction that these Guidelines do not operate to create any specific standard of care, which standard must depend upon fact-specific totality of circumstances surrounding specific quality-of-care events. The Guidelines recognize that there is not just one appropriate strategy to accomplish the goals of these Guidelines. Effective means of achieving the goals of these Guidelines vary widely depending on the type and causes of the patient's pain, the preferences of the clinician and the

**patient, the resources available at the time of care, and other concurrent issues beyond the scope of these Guidelines. See Exhibit 6; *emphasis added*.**

Here, the Government's Expert, Dr. Muir, picks out one set of opioid prescribing guidelines from the scores that exist, specifically misuses it for an unintended purpose, and then concludes that Dr. Wells committed "malpractice." There is no legitimate medical basis for this conclusion since the FSMB's opioid guidelines explicitly state that they do not establish the standard of care. Further, it is not clear from the available medical records that Dr. Wells's purported breaches in the standard of care led to any harm to ANY of the patient cases for which he was indicted by the government.

Physicians receive rudimentary training in medical malpractice, including the four elements of the tort of negligence: duty, breach, causation, and damages. In all of the cases in which Drs. Muir opines there is "malpractice," there is no documentation of adverse events, including adverse drug reaction, opioid overdose, or death. Therefore, there is no medical malpractice as a matter of medicine or law.

- 19. The use of templates and consequent redundancies in the medical record do not imply a breach in the standard of care nor do they suggest in any way that the physician was knowingly acting in bad faith or not trying to help the patient.**

Almost all physicians utilize an electronic medical record that auto-populates a template to some degree. For that reason, it is extremely common to have portions of the medical record contain identical language. This is particularly true for pertinent negatives. In other words, abnormalities that were not found. For example, "lungs clear to auscultation without rales or wheeze," is a phrase that will appear in many, many medical records. The reason is that from the time they were first-year medical students, physicians are taught to write the same unless there is an abnormality found when the doctor listens to the patient's lungs. Additionally, there are certain rote phrases in medicine that are either part of a template or are even spoken by physicians into a dictating system. In some instances, the exam technique being charted is not fully completed. An example of this is the notation:

CN II-XII grossly intact, PERRLA



Here, the physician is writing that she tested Cranial Nerves One through Twelve. She is also stating that she tested the eyes to see if the pupils were equal, round, and reactive to light and accommodation. If you ask any physician (other than a neurologist or ophthalmologist) how she specifically tested these eleven cranial nerves and whether she used a pen light and actually retrieved a Snellen Eye Chart and tested to see if the pupillary size changed when the patient's gaze changed from distance to reading, it will become obvious that the physician fudged on a few of the entries. For better or worse, this is part of the culture of modern medicine. The electronic medical record has made "fudged entries" even more common.

**20. Police reports are not part of the pain management medical record and would not have been available to Dr. Wells when he treated any of the patients in this case.**

**21. I strongly disagree with Dr. Munzing's Report in almost every aspect.** The Report is not based on valid repeatable methodologies. The report is not based on valid peer-reviewed literature. In more than 25 years of pain management, I have not encountered medical literature wherein a physician attempted to make conclusions about the medical appropriateness of controlled substance prescriptions based on state prescription databases while at the same time apparently not reviewing any of the medical records. Dr. Munzing apparently did not review medical records, physical examination findings, medical imaging, or diagnostic laboratory data. His Report is best described as junk science. The Report is extremely misleading, and he makes a number of unsubstantiated and inflammatory conclusions. As Dr. Munzing points out himself, his methods are unreliable, and conclusions cannot be definitively made from the data he reviewed.

**22. The Nevada PMP Aware Reports are unreliable and independent verification with the dispensing pharmacy is recommended because of the same.**

It is my personal practice to see my chronic pain patients on a monthly basis and to access the Nevada PMP Aware prior to each visit (such a practice is not required by the standard of care). In the many years that I have utilized PMP Aware on at least a twice-weekly basis, I have noticed that the accuracy of the Reports is largely dependent on the meticulousness of the pharmacy that enters the data. The most common mistake is that of a Nevada pharmacy dispensing a controlled substance and then not entering the same into the PMP Aware Database. This could lead a physician to believe the patient had not filled the prescription. This seems to be more common among the smaller mom and pop pharmacies rather than the large



retail pharmacies like CVS, Walmart, and Walgreen's. I have also encountered cases in which another physician wrote prescriptions for a controlled substance and the prescription was attributed to me. I have also seen cases where I wrote a prescription, and the pharmacy mistakenly attributed the prescription to another physician. All three of these error types are not rare in the Nevada PMP Aware.

PMP Aware and the Nevada State Board of Pharmacy have always acknowledged the inaccuracy of the PMP Aware Database and each Nevada PMP Aware Report comes with the following Disclaimer:

**Disclaimer:**

**...Report contents are based on data entered by dispensers and their staff, and may contain errors. The Board of Pharmacy recommends independent verification with dispensers when prudent or necessary...**

The actual Disclaimer appears below. Both the previous format and the current format of the Nevada PMP Aware contain the same Disclaimer.

**Disclaimer:**

Report contents are based on data entered by dispensers and their staff, and may contain errors. The Board of Pharmacy recommends independent verification with dispensers when prudent or necessary. Willful disclosure of prescription information may be subject to disciplinary action, civil penalties or criminal action.

From a medical standpoint, utilizing the PMP Aware Database as a basis for a criminal indictment seems extremely careless as the data themselves come with a Disclaimer that the data collected by the Nevada State Board of Pharmacy is inaccurate.

**23. Payment in cash often NOT a "red flag" for chronic pain patients.**

The fact that some of Dr. Wells's patient paid with cash for either an office visit or their prescriptions is not a "red flag." Previously, this may have been a trigger for concern, and it may still be in certain circumstances. But starting in approximately 2016, cash payment became more common in Southern Nevada as more and more insurances adopted tighter and tighter controls over approving opioid prescriptions and other controlled substances. Additionally, as health insurance pricing has skyrocketed, many patients have very high deductibles such as \$5,000

or \$10,000. Many patients end up “paying cash” for their prescriptions or office visits when in fact, they were simply meeting their deductible.

- 24. Given the ongoing shortages of controlled substances in the US, filling prescriptions at multiple pharmacies is often NOT a “red flag” and there are often legitimate reasons for patients to utilize more than one pharmacy.**

There are several circumstances wherein a patient may appear to be “pharmacy hopping” when in reality there was no alternative. For example, the pharmacy may have a small quantity of oxycodone and will partially fill the prescription or decrease the quantity of the prescription. This then requires the pain management physician to transmit another prescription to a second, third, or fourth pharmacy. The shortage of opioids is particularly true for oxycodone.

Regrettably, numerous studies have demonstrated structural racism in pain management. Many pharmacies in the Southern Nevada area routinely deny opioid prescriptions to chronic pain patients due to shortages of medication, personal beliefs about the use of opioids in chronic pain, or unfortunately, discrimination based on disability or race. In my own practice, my patients rarely encounter difficulties with filling controlled substances, however, when there is a problem, the patient is often African American. I routinely advise African American patients that the pharmacy may delay their prescription in order to “verify” that the prescription is “real.”

- 25. There is clear selection bias in the medical records chosen by the Government for the review of Dr. Wells’s pain management practice.**

The Government’s experts, Drs. Muir and Munzinger make several methodologically flawed conclusions based on reviewing only a hand-picked subset of patient charts. There is no evidence that the Government attempted to take a random sample of patient charts for analysis. More likely than not, the selected patient records were chosen specifically because they involved high doses of opioids, lacked supporting medical imaging, or otherwise had poor documentation. A busy pain clinic may serve thousands of patients. The patient examples for which Dr. Wells was indicted may actually represent only an extremely small proportion of patients. Because the denominator is unknown, it is absurd to make conclusions or implications about the proportion of patients on opioids, the proportion of patients on certain drugs, the proportion of patients on interacting medications, etc.

- 26. It is not below the standard of care for a pain management physician to treat multiple members of the same household.** There may be both genetic and environmental factors which cause pain in multiple family members.
- 27. Prescribing benzodiazepines with opioids must be done with care, however, it is not below the standard of care to do so and there may be clinical circumstances in which co-prescribing is appropriate.**

Anesthesiologists and other pain management physicians have known of the synergistic respiratory depressant effect of co-administering opioids and benzodiazepines such as Xanax or Valium. This interaction is often exploited for the purposes of administering general anesthesia to patients in surgery. The FDA did issue a black box warning about the co-administration a few years ago. Most recent studies have shown that abruptly discontinuing either opioids or benzodiazepines is a trigger that leads to destabilization and overdose in stable chronic pain patients. It is not necessarily below the standard of care to co-prescribe the two as recent studies lead to the conclusion that abrupt discontinuation of either can destabilize the patient.

- 28. Based on my review of the provided patient records used to indict and prosecute Dr. Wells, there is medical evidence supporting that more likely than not, Dr. Wells treated each of these patients with a good faith intent to provide pain management services and do the right thing for the patients.**

While there are multiple breaches in the standard of care, there are not instances in which Dr. Wells would have known, or should have known, that he would injure a patient. The fact that none of these patients apparently suffered any injuries or death is robust evidence that he used a degree of skill and care that would prevent the same.

I have reviewed all of the patients which were the basis for the Government's indictment and prosecution of Dr. Wells. While there are numerous breaches in the standard of care, there are no damages to the patients based on the medical records I reviewed. There are no instances of respiratory depression and no deaths from medication overdose. All of the patients had moderate to high opioid tolerance. Therefore, there is no breach or causation and therefore no medical malpractice. With regard to Dr. Wells's intent, Dr. Wells utilized a multi-modal medication approach, at times to a degree which may have violated the standard of care based on medication interactions. There is absolutely nothing in the medical records I reviewed that would lead a physician to the conclusion that Dr.

Wells was treating these patients in any intent other than with a good faith desire to do the right thing for the patient based on the presenting chief complaints and the data available to Dr. Wells at the time of the patient encounters.

- 29. Based on my medical education, graduate and postgraduate medical training, my 25 years of clinical experience in pain management, my review of the available medical records, and my review of other documents in this case, there is no credible evidence that Dr. Wells prescribed controlled substances to PATIENT A with the knowledge that he was breaching the standard of care, with the knowledge that he was doing so for an unlawful purpose, that he was knowingly violating the law, or that he was knowingly distributing controlled substances for any reason other than a legitimate medical purpose. To the contrary, Dr. Wells's medical history, physical exam, diagnostic imaging, diagnoses, and treatment plan, document, to a reasonable degree of medical probability (more likely than not), that his controlled substance prescriptions were issued in good faith, with good intentions, and in an attempt to utilize honest and proper medical judgment for the purposes of properly providing medical care in the State of Nevada.**

Specifically, with regard to PATIENT A, Dr. Wells properly took a medical and surgical history, properly performed a focused physical examination, properly researched past opioid use, had the patient sign an opioid contract, properly determined there was laxity of the ligamentous elements of the right knee both anteriorly and posteriorly that correlated with the patient's symptoms, and properly made a diagnosis.

Dr. Wells's pain management practice does not represent the highest level of quality of care. In fact, in my medical opinion, he does breach the standard of care for a pain management physician in some respects. Detailing the same would be beyond the scope of this report.

It is my understanding that this patient was acting at the direction of the US Government. Notwithstanding the same, there is absolutely nothing in the medical record I reviewed that would lead a physician to the conclusion that Dr. Wells was treating this "patient" in any way other than with a desire to do the right thing for the patient based on the presenting chief complaints and the data available to Dr. Wells at the time of the patient encounters.

- 30. Based on my medical education, graduate and postgraduate medical training, my 25 years of clinical experience in pain management, my review of the**

available medical records, and my review of other documents in this case, there is no credible evidence that Dr. Wells prescribed controlled substances to PATIENT B with the knowledge that he was breaching the standard of care, with the knowledge that he was doing so for an unlawful purpose, that he was knowingly violating the law, or that he was knowingly distributing controlled substances for any reason other than a legitimate medical purpose. To the contrary, Dr. Wells's medical history, physical exam, diagnostic imaging, diagnoses, and treatment plan, document, to a reasonable degree of medical probability (more likely than not), that his controlled substance prescriptions were issued in good faith, with good intentions, and in an attempt to utilize honest and proper medical judgment for the purposes of properly providing medical care in the State of Nevada.

Specifically, with regard to PATIENT B, Dr. Wells properly took a medical and surgical history, properly performed a focused physical examination, properly researched past opioid use, had the patient sign an opioid contract, properly determined there was laxity of the ligamentous elements of the right knee both anteriorly and posteriorly that correlated with the patient's symptoms, and properly made a diagnosis.

It is true that Dr. Wells's pain management practice does not represent the highest level of quality of care. In fact, in my medical opinion, he does breach the standard of care for a pain management physician in some respects. Detailing his breaches in the standard of care would be beyond the scope of this report.

31. Based on my medical education, graduate and postgraduate medical training, my 25 years of clinical experience in pain management, my review of the available medical records, and my review of other documents in this case, there is no credible evidence that Dr. Wells prescribed controlled substances to PATIENT C with the knowledge that he was breaching the standard of care, with the knowledge that he was doing so for an unlawful purpose, that he was knowingly violating the law, or that he was knowingly distributing controlled substances for any reason other than a legitimate medical purpose. To the contrary, Dr. Wells's medical history, physical exam, diagnostic imaging, diagnoses, and treatment plan, document, to a reasonable degree of medical probability (more likely than not), that his controlled substance prescriptions were issued in good faith, with good intentions, and in an attempt to utilize honest and proper medical judgment for the purposes of properly providing medical care in the State of Nevada.



Specifically, with regard to PATIENT C, there may be breaches in the standard of care, however, there is absolutely nothing in the medical record I reviewed that would lead a physician to the conclusion that Dr. Wells was treating this patient in any way other than with a desire to do the right thing for the patient based on the presenting chief complaints and the data available to Dr. Wells at the time of the patient encounters. Dr. Wells obtained medical imaging and obtained copies of reports for other imaging studies ordered by other physicians. This fact supports the idea that Dr. Wells was genuinely interested in finding a cause for the patient's pain. There are numerous painful conditions that will have no findings on medical imaging.

- 32. Based on my medical education, graduate and postgraduate medical training, my 25 years of clinical experience in pain management, my review of the available medical records, and my review of other documents in this case, there is no credible evidence that Dr. Wells prescribed controlled substances to PATIENT D with the knowledge that he was breaching the standard of care, with the knowledge that he was doing so for an unlawful purpose, that he was knowingly violating the law, or that he was knowingly distributing controlled substances for any reason other than a legitimate medical purpose. To the contrary, Dr. Wells's medical history, physical exam, diagnostic imaging, diagnoses, and treatment plan, document, to a reasonable degree of medical probability (more likely than not), that his controlled substance prescriptions were issued in good faith, with good intentions, and in an attempt to utilize honest and proper medical judgment for the purposes of properly providing medical care in the State of Nevada.**

Specifically, with regard to PATIENT D, there may be breaches in the standard of care, however, there is absolutely nothing in the medical record I reviewed that would lead a physician to the conclusion that Dr. Wells was treating this patient in any way other than with a desire to do the right thing for the patient based on the presenting chief complaints and the data available to Dr. Wells at the time of the patient encounters. Dr. Wells obtained medical imaging. The patient was also treated with multiple classes of medication. These facts support the idea that Dr. Wells was genuinely interested in finding a cause for the patient's pain. There are numerous painful conditions that will have no findings on medical imaging.

- 33. Based on my medical education, graduate and postgraduate medical training, my 25 years of clinical experience in pain management, my review of the available medical records, and my review of other documents in this case, there**

is no credible evidence that Dr. Wells prescribed controlled substances to PATIENT E with the knowledge that he was breaching the standard of care, with the knowledge that he was doing so for an unlawful purpose, that he was knowingly violating the law, or that he was knowingly distributing controlled substances for any reason other than a legitimate medical purpose. To the contrary, Dr. Wells's medical history, physical exam, diagnostic imaging, diagnoses, and treatment plan, document, to a reasonable degree of medical probability (more likely than not), that his controlled substance prescriptions were issued in good faith, with good intentions, and in an attempt to utilize honest and proper medical judgment for the purposes of properly providing medical care in the State of Nevada.

Specifically, with regard to PATIENT E, there may be breaches in the standard of care, however, there is absolutely nothing in the medical record I reviewed that would lead a physician to the conclusion that Dr. Wells was treating this patient in any way other than with a good faith desire to do the right thing for the patient based on the presenting chief complaints and the data available to Dr. Wells at the time of the patient encounters. The patient received medical imaging that demonstrated mild lumbar disc bulging. There was also imaging supporting lumbar facet arthropathy and myofascial spasm. The patient was also treated with multiple classes of medication. These facts support the idea that Dr. Wells was genuinely interested in finding a cause for the patient's pain. There are numerous painful conditions that will have no findings on medical imaging.

34. Based on my medical education, graduate and postgraduate medical training, my 25 years of clinical experience in pain management, my review of the available medical records, and my review of other documents in this case, there is no credible evidence that Dr. Wells prescribed controlled substances to PATIENT F with the knowledge that he was breaching the standard of care, with the knowledge that he was doing so for an unlawful purpose, that he was knowingly violating the law, or that he was knowingly distributing controlled substances for any reason other than a legitimate medical purpose. To the contrary, Dr. Wells's medical history, physical exam, diagnostic imaging, diagnoses, and treatment plan, document, to a reasonable degree of medical probability (more likely than not), that his controlled substance prescriptions were issued in good faith, with good intentions, and in an attempt to utilize honest and proper medical judgment for the purposes of properly providing medical care in the State of Nevada.



Specifically, with regard to PATIENT F, there may be breaches in the standard of care, however, there is absolutely nothing in the medical record I reviewed that would lead a physician to the conclusion that Dr. Wells was treating this patient in any way other than with a desire to do the right thing for the patient based on the presenting chief complaints and the data available to Dr. Wells at the time of the patient encounters. Medical imaging supporting the diagnoses of disc space narrowing was obtained. The patient was also treated with multiple classes of medication. These facts support the idea that Dr. Wells was genuinely interested in finding a cause for the patient's pain. There are numerous painful conditions that will have no findings on medical imaging.

- 35. Based on my medical education, graduate and postgraduate medical training, my 25 years of clinical experience in pain management, my review of the available medical records, and my review of other documents in this case, there is no credible evidence that Dr. Wells prescribed controlled substances to PATIENT G with the knowledge that he was breaching the standard of care, with the knowledge that he was doing so for an unlawful purpose, that he was knowingly violating the law, or that he was knowingly distributing controlled substances for any reason other than a legitimate medical purpose. To the contrary, Dr. Wells's medical history, physical exam, diagnostic imaging, diagnoses, and treatment plan, document, to a reasonable degree of medical probability (more likely than not), that his controlled substance prescriptions were issued in good faith, with good intentions, and in an attempt to utilize honest and proper medical judgment for the purposes of properly providing medical care in the State of Nevada.**

Specifically, with regard to PATIENT G, there may be breaches in the standard of care, however, there is absolutely nothing in the medical record I reviewed that would lead a physician to the conclusion that Dr. Wells was treating this patient in any way other than with a desire to do the right thing for the patient based on the presenting chief complaints and the data available to Dr. Wells at the time of the patient encounters. Dr. Wells obtained medical imaging. The patient was also treated with multiple classes of medication. These facts support the idea that Dr. Wells was genuinely interested in finding a cause for the patient's pain. There are numerous painful conditions that will have no findings on medical imaging.

- 36. Based on my medical education, graduate and postgraduate medical training, my 25 years of clinical experience in pain management, my review of the**

available medical records, and my review of other documents in this case, there is no credible evidence that Dr. Wells prescribed controlled substances to PATIENT I with the knowledge that he was breaching the standard of care, with the knowledge that he was doing so for an unlawful purpose, that he was knowingly violating the law, or that he was knowingly distributing controlled substances for any reason other than a legitimate medical purpose. To the contrary, Dr. Wells's medical history, physical exam, diagnostic imaging, diagnoses, and treatment plan, document, to a reasonable degree of medical probability (more likely than not), that his controlled substance prescriptions were issued in good faith, with good intentions, and in an attempt to utilize honest and proper medical judgment for the purposes of properly providing medical care in the State of Nevada.

Specifically, with regard to PATIENT I, there may be breaches in the standard of care, however, there is absolutely nothing in the medical record I reviewed that would lead a physician to the conclusion that Dr. Wells was treating this patient in any way other than with a desire to do the right thing for the patient based on the presenting chief complaints and the data available to Dr. Wells at the time of the patient encounters. Dr. Wells obtained medical imaging demonstrating mild facet disease in the cervical spine. The patient was also treated with multiple classes of medication. These facts support the idea that Dr. Wells was genuinely interested in finding a cause for the patient's pain.

37. Based on my medical education, graduate and postgraduate medical training, my 25 years of clinical experience in pain management, my review of the available medical records, and my review of other documents in this case, there is no credible evidence that Dr. Wells prescribed controlled substances to PATIENT J with the knowledge that he was breaching the standard of care, with the knowledge that he was doing so for an unlawful purpose, that he was knowingly violating the law, or that he was knowingly distributing controlled substances for any reason other than a legitimate medical purpose. To the contrary, Dr. Wells's medical history, physical exam, diagnostic imaging, diagnoses, and treatment plan, document, to a reasonable degree of medical probability (more likely than not), that his controlled substance prescriptions were issued in good faith, with good intentions, and in an attempt to utilize honest and proper medical judgment for the purposes of properly providing medical care in the State of Nevada.

Specifically, with regard to PATIENT J, there may be breaches in the standard of care, however, there is absolutely nothing in the medical record I reviewed that

would lead a physician to the conclusion that Dr. Wells was treating this patient in any way other than with a desire to do the right thing for the patient based on the presenting chief complaints and the data available to Dr. Wells at the time of the patient encounters. Dr. Wells obtained medical imaging and completed a fairly thorough physical examination. The patient was also treated with multiple classes of medication. These facts support the idea that Dr. Wells was genuinely interested in finding a cause for the patient's pain. There are numerous painful conditions that will have no findings on medical imaging.

- 38. Based on my medical education, graduate and postgraduate medical training, my 25 years of clinical experience in pain management, my review of the available medical records, and my review of other documents in this case, there is no credible evidence that Dr. Wells prescribed controlled substances to PATIENT K with the knowledge that he was breaching the standard of care, with the knowledge that he was doing so for an unlawful purpose, that he was knowingly violating the law, or that he was knowingly distributing controlled substances for any reason other than a legitimate medical purpose. To the contrary, Dr. Wells's medical history, physical exam, diagnostic imaging, diagnoses, and treatment plan, document, to a reasonable degree of medical probability (more likely than not), that his controlled substance prescriptions were issued in good faith, with good intentions, and in an attempt to utilize honest and proper medical judgment for the purposes of properly providing medical care in the State of Nevada.**

Specifically, with regard to PATIENT K, there may be breaches in the standard of care, however, there is absolutely nothing in the medical record I reviewed that would lead a physician to the conclusion that Dr. Wells was treating this patient in any way other than with a desire to do the right thing for the patient based on the presenting chief complaints and the data available to Dr. Wells at the time of the patient encounters. Dr. Wells obtained medical imaging of the cervical spine that correlated with the physical exam and patient complaints. The patient was also treated with multiple classes of medication. These facts support the idea that Dr. Wells was genuinely interested in finding a cause for the patient's pain. There are numerous painful conditions that will have no findings on medical imaging.

- 39. Based on my medical education, graduate and postgraduate medical training, my 25 years of clinical experience in pain management, my review of the available medical records, and my review of other documents in this case, there is no credible evidence that Dr. Wells prescribed controlled substances to**

**PATIENT L with the knowledge that he was breaching the standard of care, with the knowledge that he was doing so for an unlawful purpose, that he was knowingly violating the law, or that he was knowingly distributing controlled substances for any reason other than a legitimate medical purpose. To the contrary, Dr. Wells's medical history, physical exam, diagnostic imaging, diagnoses, and treatment plan, document, to a reasonable degree of medical probability (more likely than not), that his controlled substance prescriptions were issued in good faith, with good intentions, and in an attempt to utilize honest and proper medical judgment for the purposes of properly providing medical care in the State of Nevada.**

Specifically, with regard to PATIENT L, there are likely breaches in the standard of care, however, there is absolutely nothing in the medical record I reviewed that would lead a physician to the conclusion that Dr. Wells was treating this patient in any way other than with a desire to do the right thing for the patient based on the presenting chief complaints and the data available to Dr. Wells at the time of the patient encounters. Dr. Wells obtained medical imaging and sought to determine the cause of the pain. The patient was also treated with multiple classes of medication. These facts support the idea that Dr. Wells was genuinely interested in finding a cause for the patient's pain. There are numerous painful conditions that will have no findings on medical imaging, including shoulder pathology that may not be evident on plain films of the shoulder.

- 40. Based on my medical education, graduate and postgraduate medical training, my 25 years of clinical experience in pain management, my review of the available medical records, and my review of other documents in this case, there is no credible evidence that Dr. Wells prescribed controlled substances to PATIENT M with the knowledge that he was breaching the standard of care, with the knowledge that he was doing so for an unlawful purpose, that he was knowingly violating the law, or that he was knowingly distributing controlled substances for any reason other than a legitimate medical purpose. To the contrary, Dr. Wells's medical history, physical exam, diagnostic imaging, diagnoses, and treatment plan, document, to a reasonable degree of medical probability (more likely than not), that his controlled substance prescriptions were issued in good faith, with good intentions, and in an attempt to utilize honest and proper medical judgment for the purposes of properly providing medical care in the State of Nevada.**

Specifically, with regard to PATIENT M, there may be breaches in the standard of care, however, there is absolutely nothing in the medical record I reviewed that

would lead a physician to the conclusion that Dr. Wells was treating this patient in any way other than with a desire to do the right thing for the patient based on the presenting chief complaints and the data available to Dr. Wells at the time of the patient encounters. Dr. Wells obtained medical imaging of the lumbar spine that corroborated clinical findings. The patient was also treated with multiple classes of medication. These facts support the idea that Dr. Wells was genuinely interested in finding a cause for the patient's pain. There are numerous painful conditions that will have no findings on medical imaging.

41. **Based on my medical education, graduate and postgraduate medical training, my 25 years of clinical experience in pain management, my review of the available medical records, and my review of other documents in this case, there is no credible evidence that Dr. Wells prescribed controlled substances to PATIENT N with the knowledge that he was breaching the standard of care, with the knowledge that he was doing so for an unlawful purpose, that he was knowingly violating the law, or that he was knowingly distributing controlled substances for any reason other than a legitimate medical purpose. To the contrary, Dr. Wells's medical history, physical exam, diagnoses, and treatment plan, document, to a reasonable degree of medical probability (more likely than not), that his controlled substance prescriptions were issued in good faith, with good intentions, and in an attempt to utilize honest and proper medical judgment for the purposes of properly providing medical care in the State of Nevada.**

Specifically, with regard to PATIENT N, there are likely breaches in the standard of care, however, there is absolutely nothing in the medical record I reviewed that would lead a physician to the conclusion that Dr. Wells was treating this patient in any way other than with a desire to do the right thing for the patient based on the presenting chief complaints and the data available to Dr. Wells at the time of the patient encounters. Dr. Wells obtained vital signs and completed a physical examination. I am not able to tell if this patient had pre-existing opioid tolerance prior to being seen at the clinic. The patient was also treated with multiple classes of medication. These facts support the idea that Dr. Wells was genuinely interested in finding a cause for the patient's pain. There are numerous painful conditions that will have no findings on medical imaging.

42. **Based on my medical education, graduate and postgraduate medical training, my 25 years of clinical experience in pain management, my review of the available medical records, and my review of other documents in this case, there is no credible evidence that Dr. Wells prescribed controlled substances to**

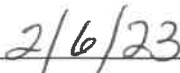


**PATIENT O with the knowledge that he was breaching the standard of care, with the knowledge that he was doing so for an unlawful purpose, that he was knowingly violating the law, or that he was knowingly distributing controlled substances for any reason other than a legitimate medical purpose. To the contrary, Dr. Wells's medical history, and treatment plan, document, to a reasonable degree of medical probability (more likely than not), that his controlled substance prescriptions were issued in good faith, with good intentions, and in an attempt to utilize honest and proper medical judgment for the purposes of properly providing medical care in the State of Nevada.**

Specifically, with regard to PATIENT O, there are likely breaches in the standard of care, however, there is absolutely nothing in the medical record I reviewed that would lead a physician to the conclusion that Dr. Wells was treating this patient in any way other than with a desire to do the right thing for the patient based on the presenting chief complaints and the data available to Dr. Wells at the time of the patient encounters. It is difficult to establish the diagnosis of endometriosis by medical imaging. The patient was also treated with multiple classes of medication. These facts support the idea that Dr. Wells was genuinely interested in finding a cause for the patient's pain. There are numerous painful conditions that will have no findings on medical imaging.

43. All of the medical and professional opinions expressed in this Report are to a reasonable degree of medical and professional probability and are based on the medical records, and other documents available; I reserve the right to change, modify, or revise my opinions if other records or additional information becomes available.
44. The medical and professional opinions expressed herein are unique to the specific factual circumstances of this particular case and therefore may not apply to other cases or factual scenarios.

  
\_\_\_\_\_  
Daniel Laird, MD

  
\_\_\_\_\_  
Date

**Exhibit 1**



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Flamingo Medical Clinic PLLC  
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Las Vegas, NV 89147  
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---

**Education/Training**

**University of Washington School of Medicine, Seattle, WA**  
Pain Medicine Fellowship, 07/95-06/96  
Anesthesiology Residency, 07/92-06/95  
Doctor of Medicine, 08/87-06/91  
Wood Library-Museum Fellow in the History of Medicine, 11/95

**Deaconess Medical Center, Spokane, WA**  
Family Practice Transitional Internship, 07/91-06/92

**University of Idaho, Moscow, ID**  
B.S. Vertebrate Zoology, 08/84-05/87  
*Summa cum laude*  
Alumni Award for Excellence  
Coach, Moscow High School Debate Team

**Liberty Baptist College, Lynchburg, VA**  
Biology Major, 08/83-06/84  
Intercollegiate Debate Team  
Chancellor's Scholarship

**Boyd School of Law, University of Nevada, Las Vegas, NV**  
Juris Doctor, 08/05-06/08,  
Society of Advocates Moot Court Team,  
Finalist, American Bar Association Western Regional Negotiation  
Competition  
CALI Awards for Excellence: (class high exam scores)  
Evidence, Professional Responsibility  
Family Law, Workers Compensation

**Seton Hill University, Greensburg, Pennsylvania**  
MFA Candidate, 2021-2023

**Current Medical Licensure**

Nevada  
Washington (Inactive)  
Colorado  
Idaho  
Wisconsin  
Alabama  
Texas  
Mississippi

**Current Legal Licensure**

Nevada

**Medical Work History**

**01/16 to Present: Flamingo Medical Clinic**  
Medical Director/ Primary Care/ Pain Management/  
Addiction Medicine/ PreP Clinic

**10/15 to 01/16: Integrated Pain Specialists**  
Staff Physician

**03/14 to 10/15: Urgent Care Extra, LLC, Las Vegas, NV**  
Staff Physician, Primary Care/ Urgent Care/ All Ages

**11/11 to 09/12: Colorado Anesthesia Associates/  
Vail Valley Medical Center, Vail, CO**  
Staff Physician/ Anesthesiology and Pain Management

**09/08 to 11/11: University of Washington School of Medicine/  
VA Puget Sound Health Care System, Seattle, WA**  
Physician Risk Manager, 2009- 2011  
Faculty Anesthesiologist, 2009- 2011  
Staff Anesthesiologist, 2008- 2009

**12/99 to 09/08: Summit Anesthesia Consultants, Inc., Las Vegas, NV**  
Shareholder Anesthesiologist, 2001- 2008  
Staff Anesthesiologist, 1999- 2001

**07/96 to 12/99: Associated Anesthesiologists of Reno, Inc., Reno, NV**  
Partner Anesthesiologist, 1998- 1999  
Staff Anesthesiologist, 1996- 1999

**Board Certification/ Fellow Status/ Professional Qualifications**

Fellow, American College of Legal Medicine, 2010- present  
Diplomate, American Board of Anesthesiology, 1998-present  
Diplomate, National Board of Medical Examiners, 1992-present  
Buprenorphine-Qualified Physician Pursuant to DATA 2000, 2016-present

**Former Professional Appointments**

Reviewer, American Society of Anesthesiologists Closed Claims Project  
Member, Committee on Professionalism, UW Department of Anesthesiology  
Member, University of Washington School of Medicine Admissions Committee  
Member, VAPSHCS Protected Peer Review Committee  
Member, VAPSHCS Clinical Executive Credentialing and Privileging Board  
Member, VAPSHCS Patient Safety Committee

**Previous and Current Professional Memberships**

International Association for the Study of Pain  
American Academy of Pain Medicine  
American College of Legal Medicine  
American Association for Justice  
Nevada Justice Association  
American Society of Anesthesiologists  
American Society of Regional Anesthesia  
Clark County Medical Society  
Nevada State Medical Association  
Nevada State Society of Anesthesiologists  
Washington State Society of Anesthesiologists

**Current and Former Special State and National Responsibilities**

Member, Board of Scientific Advisors, American Council on Science and Health,  
November 2019-present

Member, Medical Advisory Board, Dreamsickle Kids Foundation,  
(Pediatric Sickle Cell Disease Foundation)  
November 2019-present

Member, State Bar of Nevada Fee Dispute Committee, 2020-present

University of Washington School of Medicine Alumni Advisory Board/ Medical  
School Class (1991) Representative, 2010-present

Chair, Board of Directors, American Society of Anesthesiologists Political  
Action Committee (ASAPAC), 2004-2006

Member, Board of Directors, American Society of Anesthesiologists Political Action Committee (ASAPAC), 2000-2004

Delegate, House of Delegates, American Society of Anesthesiologists, 2002-2006

Member, Governmental Affairs Committee, American Society of Anesthesiologists, 2000-2006

Member, Committee on Affiliate Membership, American Society of Anesthesiologists, 2002-2003

President, Nevada State Society of Anesthesiologists, 2002-2004

**Book Chapters & Abstracts:**

Laird, D, et al. Pain management and opioids. In: Quang T (ed). Understanding the principles and practice of legal oncology. New York: McGraw Hill, 2022.

Darnall, BD, Laird, D, et al., International Stakeholder Community of Pain Experts and Leaders Call for an Urgent Action on Forced Opioid Tapering. Pain Med. 2019 Mar 1;20(3):429-433.

Laird, D. Use of Continuous End-Tidal Carbon Dioxide Tracing to Establish Pre-Hospital Esophageal Intubation as the Cause of Death in a Young Asthmatic Woman. Abstract and Poster, American College of Legal Medicine, Las Vegas, NV, February 2017

Laird, D. False Expert Testimony in a Medical Negligence Case. Abstract and Poster, American College of Legal Medicine, Las Vegas, NV, February 2017

Laird, D. Optical Forensic Examination of Questioned Medical Record Documents. Abstract and Poster, American College of Legal Medicine, Austin, TX, February 2016

Laird, D. A lack of standards, the reporting of VA providers to the National Practitioner Data Bank. Abstract and Poster, American College of Legal Medicine, Las Vegas, NV, February 2011

Ready LB, Laird D. The interface between acute and chronic pain. In: Ashburn MA (ed). The management of pain. London: Churchill Livingstone, 1998.

## **Exhibit 2**



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**Expert Review and Testimony Rates**

**Expert Affidavit of Merit**

Less than 100 pages of medical records reviewed \$1000.00 flat fee

**Expert Affidavit of Merit**

More than 100 or more pages of medical records \$300.00/ hour

Medical Records Review/ Report \$300.00/ hour

**Deposition Testimony**

(Two-hour minimum received 10 business days in advance) \$650.00/ hour

**Trial Testimony**

(Four hour minimum received 10 business days in advance,  
travel costs paid 14 business days in advance) \$650.00/ hour

**Deposition and Trial Testimony Previous Four Years**

Dillard v. Harko, LLC d/b/a Harbor Island Apartments, et al.	Nevada
Romans v. Presbyterian Healthcare Services Deposition	New Mexico
Marty v. Malin Deposition, Trial	Nevada
Regidor v. Pacificare Deposition	Nevada
Roth v. Zalik Deposition	Illinois
Jones v. Southern Hills Hospital Deposition	Nevada
Hernandez Mendez v. Loper Enterprises Deposition	Nevada
Martinez v. Silver et al. Deposition	Nevada
Mesa v. Schindler Elevator, Inc., et al.	Nevada
Murdock v. Duncan Attwood, et al.	Nevada
Johnson v. Villagran	Nevada
Goldklang v. Toia	Nevada
Sinohui v. ATS Specialized	Nevada

# **Exhibit 3**



**The New York Times**

<https://www.nytimes.com/2013/11/27/health/gynecologists-may-treat-men-board-says-in-switch.html>

## ***Gynecologists May Treat Men, Board Says in Switch***

**By Denise Grady**

Nov. 26, 2013

A professional group that certifies obstetrician-gynecologists reversed an earlier directive and said on Tuesday that its members were permitted to treat male patients for sexually transmitted infections and to screen men for anal cancer.

The statement from the American Board of Obstetrics and Gynecology eased restrictions announced in September, which said that gynecologists could lose their board certification if they treated men. Exceptions were made to allow certain procedures, but screening men who were at high risk for anal cancer was not permitted, so the September decision left some gynecologists struggling to find colleagues in other specialties to treat their male patients and to track those who were enrolled in studies.

Like cervical cancer, anal cancer is usually caused by the human papillomavirus, or HPV, which is sexually transmitted. This type of cancer is rare, but its incidence is increasing, especially among men and women infected with H.I.V.

Experts in anal cancer asked the board to reconsider its position, and some started letter-writing campaigns. Patient advocacy groups expressed worry that the prohibition would interfere with research and make it harder for male patients to find screening and treatment.

The board had said it wanted to protect the profession as a female specialty and limit the nongynecological work performed by its members. But Dr. Kenneth L. Noller, the board's director of evaluation, said board members had reconsidered and realized that gynecologists had a long tradition of treating sexually transmitted infections in both men and women, and that HPV and problems related to the virus fell into that category.

In addition, he said, the board recognized the importance of an coming study on anal cancer, funded by the federal government, and did not want to interfere with it. Finally, board members said that they did not want to “disturb the doctor-patient relationship.” Dr. Elizabeth Stier, a gynecologist at Boston Medical Center who had been forced to drop male patients who had been in her care for years, said she was happy and relieved to hear that the board had changed its mind.

“Having canceled all the men out of my clinic, I now have to un-cancel them,” Dr. Stier said. “They’ll be very happy.”

Dr. Mark H. Einstein, a gynecologic oncologist at Montefiore Medical Center in the Bronx, who had also been compelled to stop treating male patients, said: “Cool heads have prevailed. This is the best decision for our patients.”

Though most of Dr. Stier’s patients are women, she also took care of about 110 men last year who were at high risk for anal cancer. Screening tests for anal cancer involve techniques adapted from those used to screen women for cervical cancer. Dr. Stier had undergone extensive training to detect cancers and precancerous lesions in the anus, and she will be involved in the federally funded study of men and women, aimed at finding out whether screening and treating precancerous growths can prevent the cancer. The statement issued in September would have barred her from screening or treating men in that study.

A version of this article appears in print on , Section A, Page 14 of the New York edition with the headline: Gynecologists May Treat Men, Board Says in Switch

# Exhibit 4

[CLICK HERE](#)

Since 2010, VMSN has provided high-quality, comprehensive health care to members of our community who need our help. These individuals are typically low-income earners whose jobs don't include access to health insurance.

As a nonprofit health organization, VMSN provides care and support at no cost to these individuals who are falling through the cracks of our health system.

We are able to do so because of the many caring health care practitioners and other individuals who volunteer their time to help our neighbors in need, and because of the generous financial and in-kind service contributions given each year by businesses, foundations and individuals.



# The Board



**Dr. Florence Jameson, MD**  
**Founder and Board Chair**  
*Private Practice OB/GYN Physician*



**Frank "Gard" Jameson**  
**Co-founder and Treasurer**  
*Retired CPA/Certified Financial Planner,  
Professor of Philosophy, UNLV*



**Philis Beilfuss**  
*Registered Nurse*



**Shazad Contractor**

*Certified Public Accountant and licensed Marriage & Family Therapist*



**Conor P. Flynn**

*Associate General Counsel, Optum Health*



**Juan Carlos Garcia**

*General Manager, Casino Royale*



**Trang (Susan) Nguyen, PharmD, BCACP**

*Clinical Pharmacist; Associate Professor of Pharmacy Practice and  
Director of Interprofessional Education, Henderson Campus, Roseman  
University of Health Sciences*



**Eric Schmacker**

*Plan President, CEO, SilverSummit Healthplan*



**Dr. Lydia C. Wyatt, DDS**

*Dentist, Private Practice*

*Dental Director and VMSN Volunteer*

## *Administration & Operations Team*



**Desiree Zapinsky, RN**

*CEO*



**Jeanette Duncan**

*Finance Director*







**Tommy Thompson**  
*Operations Manager*



**Jessica Rodriguez**  
*Health Information Technologist*

**Pierre Malloy**  
*Clinic Custodian*

## *Medical Team*



**Michael O'Hanlan, MD**  
*Medical Director*





**Joan Klein, RN**  
*Medical Practice Manager*



**Nicole Cabrera-Heiring**  
*APRN*

**Lana Brooks**  
*APRN (Part-time)*



**Alondra Rodriguez-Martinez**  
*Diabetes Case Manager*



**Adriana Ortiz**  
*Community Health Worker*

*Community Health Worker*



**Megan Clark, RN**  
*Clinic Nurse*



**Ariel Lopez**  
*Medical Assistant*



**Monica Estrada**  
*Medical Assistant*



**Melissa Cuba**  
*Medical Assistant*





**Stacy Cruz**  
*Front Desk Assistant*



**Jeannettsy Gutierrez**  
*Front Desk Assistant*

## *Dental Team*



**Dr. Lydia C. Wyatt, DDS**  
*Volunteer Dental Director*



**George Ibrahim, DDS**  
*Dentist*



**Neda Valdez**  
Dental Health Coordinator

**Annali Contreras**  
*Dental Assistant*

## *Philanthropy Team*



**Ashley Miller**  
*Philanthropy Manager*



---

**Lacey Frantz**  
*Philanthropy Coordinator*

## *Social Behavioral Health Intervention Services Team*



**Lariza Soto, LMSW**  
*SBHIS Director*



**Karla Sarmiento, BSW**  
*Social Services Coordinator*

**Open**  
*Mental Health Provider*

## *Eligibility Team*





**Sarah Hall**  
*Eligibility Coordinator*



**Aileen Garrido**  
*Eligibility Coordinator Assistant*



**Maria Salguero**  
*Eligibility Coordinator Assistant*



**Thalia Gonzalez**  
*Eligibility Coordinator Assistant*

**Open**  
*Eligibility Assistant*

## *Pharmacy Team*



**Samson Yimamu, PD**  
*Managing Pharmacist*



**Camila Martinez, PT**  
*Senior Pharma Tech*



**Brenda Ruan**  
*Medical Assistant*

## *Volunteer & Human Resources Team*



**Kerris Clark**  
*Volunteer Coordinator*



**Danait Fessahaie**  
*HR Manager*

**Volunteers in Medicine of Southern Nevada**

1240 N. Martin Luther King Blvd., Las Vegas, NV 89106

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702-967-0538 (Fax) (tel:702-967-0538) | [info@vmsn.org](mailto:info@vmsn.org) (mailto:info@vmsn.org)

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# Exhibit 5

**ACGME Program Requirements for  
Graduate Medical Education  
in Obstetrics and Gynecology**

ACGME-approved focused revision: September 17, 2022; effective September 17, 2022  
Revised Common Program Requirements incorporated July 1, 2022

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## ACGME Program Requirements for Graduate Medical Education in Obstetrics and Gynecology

### Common Program Requirements (Residency) are in BOLD

Where applicable, text in italics describes the underlying philosophy of the requirements in that section. These philosophic statements are not program requirements and are therefore not citable.

#### Introduction

**Int.A.** *Graduate medical education is the crucial step of professional development between medical school and autonomous clinical practice. It is in this vital phase of the continuum of medical education that residents learn to provide optimal patient care under the supervision of faculty members who not only instruct, but serve as role models of excellence, compassion, professionalism, and scholarship.*

*Graduate medical education transforms medical students into physician scholars who care for the patient, family, and a diverse community; create and integrate new knowledge into practice; and educate future generations of physicians to serve the public. Practice patterns established during graduate medical education persist many years later.*

*Graduate medical education has as a core tenet the graded authority and responsibility for patient care. The care of patients is undertaken with appropriate faculty supervision and conditional independence, allowing residents to attain the knowledge, skills, attitudes, and empathy required for autonomous practice. Graduate medical education develops physicians who focus on excellence in delivery of safe, equitable, affordable, quality care; and the health of the populations they serve. Graduate medical education values the strength that a diverse group of physicians brings to medical care.*

*Graduate medical education occurs in clinical settings that establish the foundation for practice-based and lifelong learning. The professional development of the physician, begun in medical school, continues through faculty modeling of the effacement of self-interest in a humanistic environment that emphasizes joy in curiosity, problem-solving, academic rigor, and discovery. This transformation is often physically, emotionally, and intellectually demanding and occurs in a variety of clinical learning environments committed to graduate medical education and the well-being of patients, residents, fellows, faculty members, students, and all members of the health care team.*

#### **Int.B.** Definition of Specialty

Obstetrician gynecologists are physicians who, by virtue of satisfactory completion of a defined course of graduate medical education, possess special knowledge, skills, and professional capability in the medical and surgical care of the female reproductive system across the life span and women's health

conditions, such that it distinguishes them from other physicians and enables them to serve as primary physicians for women, and as consultants to other physicians.

**Int.C. Length of Educational Program**

The educational program in obstetrics and gynecology must be 48 months in length. <sup>(Core)</sup>\*

**I. Oversight**

**I.A. Sponsoring Institution**

*The Sponsoring Institution is the organization or entity that assumes the ultimate financial and academic responsibility for a program of graduate medical education, consistent with the ACGME Institutional Requirements.*

*When the Sponsoring Institution is not a rotation site for the program, the most commonly utilized site of clinical activity for the program is the primary clinical site.*

**Background and Intent:** Participating sites will reflect the health care needs of the community and the educational needs of the residents. A wide variety of organizations may provide a robust educational experience and, thus, Sponsoring Institutions and participating sites may encompass inpatient and outpatient settings including, but not limited to a university, a medical school, a teaching hospital, a nursing home, a school of public health, a health department, a public health agency, an organized health care delivery system, a medical examiner's office, an educational consortium, a teaching health center, a physician group practice, federally qualified health center, or an educational foundation.

**I.A.1. The program must be sponsored by one ACGME-accredited Sponsoring Institution. <sup>(Core)</sup>**

**I.B. Participating Sites**

*A participating site is an organization providing educational experiences or educational assignments/rotations for residents.*

**I.B.1. The program, with approval of its Sponsoring Institution, must designate a primary clinical site. <sup>(Core)</sup>**

**I.B.1.a) The primary clinical site should also be the clinical site for at least one other ACGME-accredited residency program in another specialty. <sup>(Core)</sup>**

**I.B.2. There must be a program letter of agreement (PLA) between the program and each participating site that governs the relationship between the program and the participating site providing a required assignment. <sup>(Core)</sup>**

**I.B.2.a) The PLA must:**

**I.B.2.a).(1) be renewed at least every 10 years; and, (Core)**

**I.B.2.a).(2) be approved by the designated institutional official (DIO). (Core)**

**I.B.3. The program must monitor the clinical learning and working environment at all participating sites. (Core)**

**I.B.3.a) At each participating site there must be one faculty member, designated by the program director as the site director, who is accountable for resident education at that site, in collaboration with the program director. (Core)**

**Background and Intent:** While all residency programs must be sponsored by a single ACGME-accredited Sponsoring Institution, many programs will utilize other clinical settings to provide required or elective training experiences. At times it is appropriate to utilize community sites that are not owned by or affiliated with the Sponsoring Institution. Some of these sites may be remote for geographic, transportation, or communication issues. When utilizing such sites the program must ensure the quality of the educational experience. The requirements under I.B.3. are intended to ensure that this will be the case.

**Suggested elements to be considered in PLAs will be found in the ACGME Program Director's Guide to the Common Program Requirements. These include:**

- **Identifying the faculty members who will assume educational and supervisory responsibility for residents**
- **Specifying the responsibilities for teaching, supervision, and formal evaluation of residents**
- **Specifying the duration and content of the educational experience**
- **Stating the policies and procedures that will govern resident education during the assignment**

**I.B.4. The program director must submit any additions or deletions of participating sites routinely providing an educational experience, required for all residents, of one month full time equivalent (FTE) or more through the ACGME's Accreditation Data System (ADS). (Core)**

**I.C. The program, in partnership with its Sponsoring Institution, must engage in practices that focus on mission-driven, ongoing, systematic recruitment and retention of a diverse and inclusive workforce of residents, fellows (if present), faculty members, senior administrative staff members, and other relevant members of its academic community. (Core)**

**Background and Intent:** It is expected that the Sponsoring Institution has, and programs implement, policies and procedures related to recruitment and retention of minorities underrepresented in medicine and medical leadership in accordance with the Sponsoring Institution's mission and aims. The program's annual evaluation must

**include an assessment of the program's efforts to recruit and retain a diverse workforce, as noted in V.C.1.c).(5).(c).**

**I.D. Resources**

**I.D.1. The program, in partnership with its Sponsoring Institution, must ensure the availability of adequate resources for resident education.**  
(Core)

I.D.1.a) Inpatient facilities, including a labor and delivery unit, operating rooms, recovery room(s), intensive care unit(s), blood bank(s), diagnostic laboratories, and imaging services, must be regularly available and accessible on an emergency basis. (Core)

I.D.1.b) Ambulatory care facilities must be regularly available and adequately equipped. (Core)

I.D.1.c) Residents must have access to hospital-based consultative services in the major medical and surgical disciplines. (Core)

**Specialty-Specific Background and Intent:** It is expected that programs that depend on nearby facility(ies) to provide medical and surgical critical care have established a clear threshold for the transfer of patient care, plans for the transfer of patient care, and have current written agreement(s) in place with the accepting facility(ies).

I.D.1.d) There must be space and equipment for the educational program, including office space for residents which must include computer workstations that provide access to electronic health records and space for interprofessional discussions regarding patient care to maintain patient confidentiality, classroom space for educational activities, and access to simulation resources. (Core)

I.D.1.e) The patient population on which the educational program is based must be sufficient in volume and variety so that the broad spectrum of experiences necessary to meet the educational objectives will be provided. (Core)

**I.D.2. The program, in partnership with its Sponsoring Institution, must ensure healthy and safe learning and working environments that promote resident well-being and provide for:** (Core)

**I.D.2.a) access to food while on duty;** (Core)

**I.D.2.b) safe, quiet, clean, and private sleep/rest facilities available and accessible for residents with proximity appropriate for safe patient care;** (Core)

**Background and Intent:** Care of patients within a hospital or health system occurs continually through the day and night. Such care requires that residents function at their peak abilities, which requires the work environment to provide them with the

ability to meet their basic needs within proximity of their clinical responsibilities. Access to food and rest are examples of these basic needs, which must be met while residents are working. Residents should have access to refrigeration where food may be stored. Food should be available when residents are required to be in the hospital overnight. Rest facilities are necessary, even when overnight call is not required, to accommodate the fatigued resident.

- I.D.2.c)** clean and private facilities for lactation that have refrigeration capabilities, with proximity appropriate for safe patient care;  
(Core)

**Background and Intent:** Sites must provide private and clean locations where residents may lactate and store the milk within a refrigerator. These locations should be in close proximity to clinical responsibilities. It would be helpful to have additional support within these locations that may assist the resident with the continued care of patients, such as a computer and a phone. While space is important, the time required for lactation is also critical for the well-being of the resident and the resident's family, as outlined in VI.C.1.d).(1).

- I.D.2.d)** security and safety measures appropriate to the participating site; and, (Core)

- I.D.2.e)** accommodations for residents with disabilities consistent with the Sponsoring Institution's policy. (Core)

- I.D.3.** Residents must have ready access to specialty-specific and other appropriate reference material in print or electronic format. This must include access to electronic medical literature databases with full text capabilities. (Core)

- I.D.4.** The program's educational and clinical resources must be adequate to support the number of residents appointed to the program. (Core)

- I.E.** The presence of other learners and other care providers, including, but not limited to, residents from other programs, subspecialty fellows, and advanced practice providers, must enrich the appointed residents' education. (Core)

- I.E.1.** The program must report circumstances when the presence of other learners has interfered with the residents' education to the DIO and Graduate Medical Education Committee (GMEC). (Core)

**Background and Intent:** The clinical learning environment has become increasingly complex and often includes care providers, students, and post-graduate residents and fellows from multiple disciplines. The presence of these practitioners and their learners enriches the learning environment. Programs have a responsibility to monitor the learning environment to ensure that residents' education is not compromised by the presence of other providers and learners.

## **II. Personnel**

**II.A. Program Director**

**II.A.1. There must be one faculty member appointed as program director with authority and accountability for the overall program, including compliance with all applicable program requirements. (Core)**

**II.A.1.a) The Sponsoring Institution's GMEC must approve a change in program director. (Core)**

**II.A.1.b) Final approval of the program director resides with the Review Committee. (Core)**

**Background and Intent:** While the ACGME recognizes the value of input from numerous individuals in the management of a residency, a single individual must be designated as program director and have overall responsibility for the program. The program director's nomination is reviewed and approved by the GMEC. Final approval of the program director resides with the applicable ACGME Review Committee.

**II.A.1.c) The program must demonstrate retention of the program director for a length of time adequate to maintain continuity of leadership and program stability. (Core)**

**Background and Intent:** The success of residency programs is generally enhanced by continuity in the program director position. The professional activities required of a program director are unique and complex and take time to master. All programs are encouraged to undertake succession planning to facilitate program stability when there is necessary turnover in the program director position.

**II.A.2. The program director and, as applicable, the program's leadership team, must be provided with support adequate for administration of the program based upon its size and configuration. (Core)**

**II.A.2.a) At a minimum, the program director must be provided with the dedicated time and support specified below for administration of the program. Additional support for program leadership must be provided as specified below. This additional support may be for the program director only or divided among the program director and one or more associate (or assistant) program directors. (Core)**

Number of Approved Resident Positions	Minimum Support Required (FTE) for the Program Director	Minimum Additional Support Required (FTE) for Program Leadership in Aggregate
7-10	0.4	-
11-15	0.5	-
16-20	0.5	0.1
21-25	0.5	0.2
26-30	0.5	0.3
31-35	0.5	0.4
36-40	0.5	0.5



41-45	0.5	0.6
46-50	0.5	0.7
51-55	0.5	0.8
56-60	0.5	0.9
61-65	0.5	1.0
66-70	0.5	1.1
71-75	0.5	1.2
76-80	0.5	1.3

**Background and Intent:** To achieve successful graduate medical education, individuals serving as education and administrative leaders of residency programs, as well as those significantly engaged in the education, supervision, evaluation, and mentoring of residents, must have sufficient dedicated professional time to perform the vital activities required to sustain an accredited program.

The ultimate outcome of graduate medical education is excellence in resident education and patient care.

The program director and, as applicable, the program leadership team, devote a portion of their professional effort to the oversight and management of the residency program, as defined in II.A.4.-II.A.4.a).(16). Both provision of support for the time required for the leadership effort and flexibility regarding how this support is provided are important. Programs, in partnership with their Sponsoring Institutions, may provide support for this time in a variety of ways. Examples of support may include, but are not limited to, salary support, supplemental compensation, educational value units, or relief of time from other professional duties.

Program directors and, as applicable, members of the program leadership team, who are new to the role may need to devote additional time to program oversight and management initially as they learn and become proficient in administering the program. It is suggested that during this initial period the support described above be increased as needed.

In addition, it is important to remember that the dedicated time and support requirement for ACGME activities is a *minimum*, recognizing that, depending on the unique needs of the program, additional support may be warranted.

#### **II.A.3. Qualifications of the program director:**

**II.A.3.a) must include specialty expertise and at least three years of documented educational and/or administrative experience, or qualifications acceptable to the Review Committee; (Core)**

**Background and Intent:** Leading a program requires knowledge and skills that are established during residency and subsequently further developed. The time period from completion of residency until assuming the role of program director allows the individual to cultivate leadership abilities while becoming professionally established. The three-year period is intended for the individual's professional maturation.



The broad allowance for educational and/or administrative experience recognizes that strong leaders arise through diverse pathways. These areas of expertise are important when identifying and appointing a program director. The choice of a program director should be informed by the mission of the program and the needs of the community.

In certain circumstances, the program and Sponsoring Institution may propose and the Review Committee may accept a candidate for program director who fulfills these goals but does not meet the three-year minimum.

- II.A.3.b)** must include current certification in the specialty for which they are the program director by the American Board of Obstetrics and Gynecology (ABOG) or by the American Osteopathic Board of Obstetrics and Gynecology, or specialty qualifications that are acceptable to the Review Committee; <sup>(Core)</sup>
- II.A.3.c)** must include current medical licensure and appropriate medical staff appointment; and, <sup>(Core)</sup>
- II.A.3.d)** must include ongoing clinical activity. <sup>(Core)</sup>

**Background and Intent:** A program director is a role model for faculty members and residents. The program director must participate in clinical activity consistent with the specialty. This activity will allow the program director to role model the Core Competencies for the faculty members and residents.

**II.A.4. Program Director Responsibilities**

The program director must have responsibility, authority, and accountability for: administration and operations; teaching and scholarly activity; resident recruitment and selection, evaluation, and promotion of residents, and disciplinary action; supervision of residents; and resident education in the context of patient care. <sup>(Core)</sup>

**II.A.4.a) The program director must:**

- II.A.4.a).(1)** be a role model of professionalism; <sup>(Core)</sup>

**Background and Intent:** The program director, as the leader of the program, must serve as a role model to residents in addition to fulfilling the technical aspects of the role. As residents are expected to demonstrate compassion, integrity, and respect for others, they must be able to look to the program director as an exemplar. It is of utmost importance, therefore, that the program director model outstanding professionalism, high quality patient care, educational excellence, and a scholarly approach to work. The program director creates an environment where respectful discussion is welcome, with the goal of continued improvement of the educational experience.

- II.A.4.a).(2)** design and conduct the program in a fashion consistent with the needs of the community, the

**mission(s) of the Sponsoring Institution, and the mission(s) of the program;** <sup>(Core)</sup>

**Background and Intent:** The mission of institutions participating in graduate medical education is to improve the health of the public. Each community has health needs that vary based upon location and demographics. Programs must understand the social determinants of health of the populations they serve and incorporate them in the design and implementation of the program curriculum, with the ultimate goal of addressing these needs and health disparities.

**II.A.4.a).(3)** administer and maintain a learning environment conducive to educating the residents in each of the ACGME Competency domains; <sup>(Core)</sup>

**Background and Intent:** The program director may establish a leadership team to assist in the accomplishment of program goals. Residency programs can be highly complex. In a complex organization, the leader typically has the ability to delegate authority to others, yet remains accountable. The leadership team may include physician and non-physician personnel with varying levels of education, training, and experience.

**II.A.4.a).(4)** develop and oversee a process to evaluate candidates prior to approval as program faculty members for participation in the residency program education and at least annually thereafter, as outlined in V.B.; <sup>(Core)</sup>

**II.A.4.a).(5)** have the authority to approve program faculty members for participation in the residency program education at all sites; <sup>(Core)</sup>

**II.A.4.a).(6)** have the authority to remove program faculty members from participation in the residency program education at all sites; <sup>(Core)</sup>

**II.A.4.a).(7)** have the authority to remove residents from supervising interactions and/or learning environments that do not meet the standards of the program; <sup>(Core)</sup>

**Background and Intent:** The program director has the responsibility to ensure that all who educate residents effectively role model the Core Competencies. Working with a resident is a privilege that is earned through effective teaching and professional role modeling. This privilege may be removed by the program director when the standards of the clinical learning environment are not met.

There may be faculty in a department who are not part of the educational program, and the program director controls who is teaching the residents.

**II.A.4.a).(8)** submit accurate and complete information required and requested by the DIO, GMEC, and ACGME; <sup>(Core)</sup>

- II.A.4.a).(9)** provide applicants who are offered an interview with information related to the applicant's eligibility for the relevant specialty board examination(s); <sup>(Core)</sup>
- II.A.4.a).(10)** provide a learning and working environment in which residents have the opportunity to raise concerns and provide feedback in a confidential manner as appropriate, without fear of intimidation or retaliation; <sup>(Core)</sup>
- II.A.4.a).(11)** ensure the program's compliance with the Sponsoring Institution's policies and procedures related to grievances and due process; <sup>(Core)</sup>
- II.A.4.a).(12)** ensure the program's compliance with the Sponsoring Institution's policies and procedures for due process when action is taken to suspend or dismiss, not to promote, or not to renew the appointment of a resident; <sup>(Core)</sup>

**Background and Intent:** A program does not operate independently of its Sponsoring Institution. It is expected that the program director will be aware of the Sponsoring Institution's policies and procedures, and will ensure they are followed by the program's leadership, faculty members, support personnel, and residents.

- II.A.4.a).(13)** ensure the program's compliance with the Sponsoring Institution's policies and procedures on employment and non-discrimination; <sup>(Core)</sup>
- II.A.4.a).(13).(a)** Residents must not be required to sign a non-competition guarantee or restrictive covenant. <sup>(Core)</sup>
- II.A.4.a).(14)** document verification of program completion for all graduating residents within 30 days; <sup>(Core)</sup>
- II.A.4.a).(15)** provide verification of an individual resident's completion upon the resident's request, within 30 days; and, <sup>(Core)</sup>

**Background and Intent:** Primary verification of graduate medical education is important to credentialing of physicians for further training and practice. Such verification must be accurate and timely. Sponsoring Institution and program policies for record retention are important to facilitate timely documentation of residents who have previously completed the program. Residents who leave the program prior to completion also require timely documentation of their summative evaluation.

- II.A.4.a).(16)** obtain review and approval of the Sponsoring Institution's DIO before submitting information or requests to the ACGME, as required in the Institutional Requirements and outlined in the ACGME Program

**Director's Guide to the Common Program  
Requirements.** (Core)

**II.B. Faculty**

*Faculty members are a foundational element of graduate medical education – faculty members teach residents how to care for patients. Faculty members provide an important bridge allowing residents to grow and become practice-ready, ensuring that patients receive the highest quality of care. They are role models for future generations of physicians by demonstrating compassion, commitment to excellence in teaching and patient care, professionalism, and a dedication to lifelong learning. Faculty members experience the pride and joy of fostering the growth and development of future colleagues. The care they provide is enhanced by the opportunity to teach. By employing a scholarly approach to patient care, faculty members, through the graduate medical education system, improve the health of the individual and the population.*

*Faculty members ensure that patients receive the level of care expected from a specialist in the field. They recognize and respond to the needs of the patients, residents, community, and institution. Faculty members provide appropriate levels of supervision to promote patient safety. Faculty members create an effective learning environment by acting in a professional manner and attending to the well-being of the residents and themselves.*

**Background and Intent:** “Faculty” refers to the entire teaching force responsible for educating residents. The term “faculty,” including “core faculty,” does not imply or require an academic appointment.

**II.B.1. At each participating site, there must be a sufficient number of faculty members with competence to instruct and supervise all residents at that location.** (Core)

**II.B.1.a)** The program director should identify a qualified individual as a Subspecialty Faculty Educator in each of the following subspecialties of obstetrics and gynecology: complex family planning; female pelvic medicine and reconstructive surgery; gynecologic oncology; maternal-fetal medicine; and reproductive endocrinology and infertility. (Detail)

**II.B.1.a).(1)** The Subspecialty Faculty Educator should be:

**II.B.1.a).(1).(a)** currently certified in the subspecialty by ABOG or AOBOG, or possess qualifications that are acceptable to the Review Committee, and, (Detail)

**II.B.1.a).(1).(b)** accountable for the coordination of residents' educational experiences in the respective subspecialty, in collaboration with the program director. (Detail)

**II.B.2. Faculty members must:****II.B.2.a) be role models of professionalism; (Core)****II.B.2.b) demonstrate commitment to the delivery of safe, quality, cost-effective, patient-centered care; (Core)****Background and Intent: Patients have the right to expect quality, cost-effective care with patient safety at its core. The foundation for meeting this expectation is formed during residency and fellowship. Faculty members model these goals and continually strive for improvement in care and cost, embracing a commitment to the patient and the community they serve.****II.B.2.c) demonstrate a strong interest in the education of residents; (Core)****II.B.2.d) devote sufficient time to the educational program to fulfill their supervisory and teaching responsibilities; (Core)****II.B.2.e) administer and maintain an educational environment conducive to educating residents; (Core)****II.B.2.f) regularly participate in organized clinical discussions, rounds, journal clubs, and conferences; and, (Core)****II.B.2.g) pursue faculty development designed to enhance their skills at least annually; (Core)****Background and Intent: Faculty development is intended to describe structured programming developed for the purpose of enhancing transference of knowledge, skill, and behavior from the educator to the learner. Faculty development may occur in a variety of configurations (lecture, workshop, etc.) using internal and/or external resources. Programming is typically needs-based (individual or group) and may be specific to the institution or the program. Faculty development programming is to be reported for the residency program faculty in the aggregate.****II.B.2.g).(1) as educators; (Core)****II.B.2.g).(2) in quality improvement and patient safety; (Core)****II.B.2.g).(3) in fostering their own and their residents' well-being; and, (Core)****II.B.2.g).(4) in patient care based on their practice-based learning and improvement efforts. (Core)****Background and Intent: Practice-based learning serves as the foundation for the practice of medicine. Through a systematic analysis of one's practice and review of the literature, one is able to make adjustments that improve patient outcomes and care.**

**Thoughtful consideration to practice-based analysis improves quality of care, as well as patient safety. This allows faculty members to serve as role models for residents in practice-based learning.**

- II.B.2.h) provide on-site physician faculty member supervision when residents are on duty in the inpatient hospital. <sup>(Core)</sup>
- II.B.2.h).(1) On the labor and delivery unit, on-site physician faculty member supervision must be provided by an obstetrics and gynecology physician. <sup>(Core)</sup>
- II.B.2.h).(2) Members of the physician faculty must be immediately available to a resident if clinical activity is taking place in the operating rooms and/or labor and delivery areas. <sup>(Core)</sup>
- II.B.2.h).(3) If the program director judges that the size and nature of the patient population does not require a 24-hour on-site presence of residents or physician faculty members, this situation must be carefully defined, and must receive prior approval from the Review Committee. <sup>(Core)</sup>

### **II.B.3. Faculty Qualifications**

- II.B.3.a) **Faculty members must have appropriate qualifications in their field and hold appropriate institutional appointments.** <sup>(Core)</sup>
- II.B.3.b) **Physician faculty members must:**
- II.B.3.b).(1) **have current certification in the specialty by the American Board of Obstetrics and Gynecology (ABOG) or the American Osteopathic Board of Obstetrics and Gynecology, or possess qualifications judged acceptable to the Review Committee.** <sup>(Core)</sup>
- II.B.3.c) **Any non-physician faculty members who participate in residency program education must be approved by the program director.** <sup>(Core)</sup>

**Background and Intent: The provision of optimal and safe patient care requires a team approach. The education of residents by non-physician educators enables the resident to better manage patient care and provides valuable advancement of the residents' knowledge. Furthermore, other individuals contribute to the education of the resident in the basic science of the specialty or in research methodology. If the program director determines that the contribution of a non-physician individual is significant to the education of the residents, the program director may designate the individual as a program faculty member or a program core faculty member.**

### **II.B.4. Core Faculty**

**Core faculty members must have a significant role in the education and supervision of residents and must devote a significant portion of their entire effort to resident education and/or administration, and must, as a component of their activities, teach, evaluate, and provide formative feedback to residents.** <sup>(Core)</sup>

**Background and Intent:** Core faculty members are critical to the success of resident education. They support the program leadership in developing, implementing, and assessing curriculum, mentoring residents, and assessing residents' progress toward achievement of competence in and the independent practice of the specialty. Core faculty members should be selected for their broad knowledge of and involvement in the program, permitting them to effectively evaluate the program. Core faculty members may also be selected for their specific expertise and unique contribution to the program. Core faculty members are engaged in a broad range of activities, which may vary across programs and specialties. Core faculty members provide clinical teaching and supervision of residents, and also participate in non-clinical activities related to resident education and program administration. Examples of these non-clinical activities include, but are not limited to, interviewing and selecting resident applicants, providing didactic instruction, mentoring residents, simulation exercises, completing the annual ACGME Faculty Survey, and participating on the program's Clinical Competency Committee, Program Evaluation Committee, and other GME committees.

- II.B.4.a)** **Core faculty members must be designated by the program director.** <sup>(Core)</sup>
- II.B.4.b)** **Core faculty members must complete the annual ACGME Faculty Survey.** <sup>(Core)</sup>
- II.B.4.c)** Programs with 12 or fewer residents must have a minimum of three core physician faculty members in addition to the program director. <sup>(Core)</sup>
- II.B.4.d)** Programs with more than 12 residents must have a minimum of one core physician faculty member, in addition to the program director, for every four residents. <sup>(Core)</sup>
- II.C. Program Coordinator**
- II.C.1.** **There must be a program coordinator.** <sup>(Core)</sup>
- II.C.2.** **The program coordinator must be provided with dedicated time and support adequate for administration of the program based upon its size and configuration.** <sup>(Core)</sup>
- II.C.2.a)** At a minimum, the program coordinator must be provided with the dedicated time and support specified below for administration of the program. Additional administrative support must be provided based on program size as follows: <sup>(Core)</sup>



Number of Approved Resident Positions	Minimum FTE Required for Coordinator Support	Minimum Additional Aggregate FTE Required for Administration of the Program
7-10	0.7	-
11-15	0.8	-
16-20	0.9	-
21-25	1.0	-
26-30	1.0	0.1
31-35	1.0	0.2
36-40	1.0	0.3
41-45	1.0	0.4
46-50	1.0	0.5
51-55	1.0	0.6
56-60	1.0	0.7
61-65	1.0	0.8
66-70	1.0	0.9
71-75	1.0	1.0
76-80	1.0	1.1

**Background and Intent:** The requirement does not address the source of funding required to provide the specified salary support.

Each program requires a lead administrative person, frequently referred to as a program coordinator, administrator, or as otherwise titled by the institution. This person will frequently manage the day-to-day operations of the program and serve as an important liaison and facilitator between the learners, faculty and other staff members, and the ACGME. Individuals serving in this role are recognized as program coordinators by the ACGME.

The program coordinator is a key member of the leadership team and is critical to the success of the program. As such, the program coordinator must possess skills in leadership and personnel management appropriate to the complexity of the program. Program coordinators are expected to develop in-depth knowledge of the ACGME and Program Requirements, including policies and procedures. Program coordinators assist the program director in meeting accreditation requirements, educational programming, and support of residents.

Programs, in partnership with their Sponsoring Institutions, should encourage the professional development of their program coordinators and avail them of opportunities for both professional and personal growth. Programs with fewer residents may not require a full-time coordinator; one coordinator may support more than one program.

The minimum required dedicated time and support specified in II.C.2.a) is inclusive of activities directly related to administration of the accredited program. It is understood that coordinators often have additional responsibilities, beyond those directly related to program administration, including, but not limited to, departmental administrative responsibilities, medical school clerkships, planning lectures that are not solely intended for the accredited program, and mandatory reporting for entities other than

the ACGME. Assignment of these other responsibilities will necessitate consideration of allocation of additional support so as not to preclude the coordinator from devoting the time specified above solely to administrative activities that support the accredited program.

In addition, it is important to remember that the dedicated time and support requirement for ACGME activities is a minimum, recognizing that, depending on the unique needs of the program, additional support may be warranted.

#### **II.D. Other Program Personnel**

The program, in partnership with its Sponsoring Institution, must jointly ensure the availability of necessary personnel for the effective administration of the program. <sup>(Core)</sup>

**Background and Intent:** Multiple personnel may be required to effectively administer a program. These may include staff members with clerical skills, project managers, education experts, and staff members to maintain electronic communication for the program. These personnel may support more than one program in more than one discipline.

### **III. Resident Appointments**

#### **III.A. Eligibility Requirements**

**III.A.1.** An applicant must meet one of the following qualifications to be eligible for appointment to an ACGME-accredited program: <sup>(Core)</sup>

**III.A.1.a)** graduation from a medical school in the United States or Canada, accredited by the Liaison Committee on Medical Education (LCME) or graduation from a college of osteopathic medicine in the United States, accredited by the American Osteopathic Association Commission on Osteopathic College Accreditation (AOACOCA); or, <sup>(Core)</sup>

**III.A.1.b)** graduation from a medical school outside of the United States or Canada, and meeting one of the following additional qualifications: <sup>(Core)</sup>

**III.A.1.b).(1)** holding a currently valid certificate from the Educational Commission for Foreign Medical Graduates (ECFMG) prior to appointment; or, <sup>(Core)</sup>

**III.A.1.b).(2)** holding a full and unrestricted license to practice medicine in the United States licensing jurisdiction in which the ACGME-accredited program is located. <sup>(Core)</sup>

**III.A.2.** All prerequisite post-graduate clinical education required for initial entry or transfer into ACGME-accredited residency programs must be completed in ACGME-accredited residency programs, AOA-approved residency programs, Royal College of Physicians and

**Surgeons of Canada (RCPSC)-accredited or College of Family Physicians of Canada (CFPC)-accredited residency programs located in Canada, or in residency programs with ACGME International (ACGME-I) Advanced Specialty Accreditation. (Core)**

- III.A.2.a)                      Residency programs must receive verification of each resident's level of competency in the required clinical field using ACGME, CanMEDS, or ACGME-I Milestones evaluations from the prior training program upon matriculation. (Core)**

**Background and Intent: Programs with ACGME-I Foundational Accreditation or from institutions with ACGME-I accreditation do not qualify unless the program has also achieved ACGME-I Advanced Specialty Accreditation. To ensure entrants into ACGME-accredited programs from ACGME-I programs have attained the prerequisite milestones for this training, they must be from programs that have ACGME-I Advanced Specialty Accreditation.**

- III.A.3.                      A physician who has completed a residency program that was not accredited by ACGME, AOA, RCPSC, CFPC, or ACGME-I (with Advanced Specialty Accreditation) may enter an ACGME-accredited residency program in the same specialty at the PGY-1 level and, at the discretion of the program director of the ACGME-accredited program and with approval by the GMEC, may be advanced to the PGY-2 level based on ACGME Milestones evaluations at the ACGME-accredited program. This provision applies only to entry into residency in those specialties for which an initial clinical year is not required for entry. (Core)**

- III.B.                      The program director must not appoint more residents than approved by the Review Committee. (Core)**

- III.B.1.                      All complement increases must be approved by the Review Committee. (Core)**

- III.B.2.                      There should be at least three approved categorical positions per PGY level. (Core)**

- III.C.                      Resident Transfers**

**The program must obtain verification of previous educational experiences and a summative competency-based performance evaluation prior to acceptance of a transferring resident, and Milestones evaluations upon matriculation. (Core)**

- IV.                      Educational Program**

***The ACGME accreditation system is designed to encourage excellence and innovation in graduate medical education regardless of the organizational affiliation, size, or location of the program.***

***The educational program must support the development of knowledgeable, skillful physicians who provide compassionate care.***

***In addition, the program is expected to define its specific program aims consistent with the overall mission of its Sponsoring Institution, the needs of the community it serves and that its graduates will serve, and the distinctive capabilities of physicians it intends to graduate. While programs must demonstrate substantial compliance with the Common and specialty-specific Program Requirements, it is recognized that within this framework, programs may place different emphasis on research, leadership, public health, etc. It is expected that the program aims will reflect the nuanced program-specific goals for it and its graduates; for example, it is expected that a program aiming to prepare physician-scientists will have a different curriculum from one focusing on community health.***

**IV.A. The curriculum must contain the following educational components; (Core)**

**IV.A.1. a set of program aims consistent with the Sponsoring Institution's mission, the needs of the community it serves, and the desired distinctive capabilities of its graduates; (Core)**

**IV.A.1.a) The program's aims must be made available to program applicants, residents, and faculty members. (Core)**

**IV.A.2. competency-based goals and objectives for each educational experience designed to promote progress on a trajectory to autonomous practice. These must be distributed, reviewed, and available to residents and faculty members; (Core)**

**Background and Intent:** The trajectory to autonomous practice is documented by Milestones evaluation. The Milestones detail the progress of a resident in attaining skill in each competency domain. They are developed by each specialty group and allow evaluation based on observable behaviors. Milestones are considered formative and should be used to identify learning needs. This may lead to focused or general curricular revision in any given program or to individualized learning plans for any specific resident.

**IV.A.3. delineation of resident responsibilities for patient care, progressive responsibility for patient management, and graded supervision; (Core)**

**Background and Intent:** These responsibilities may generally be described by PGY level and specifically by Milestones progress as determined by the Clinical Competency Committee. This approach encourages the transition to competency-based education. An advanced learner may be granted more responsibility independent of PGY level and a learner needing more time to accomplish a certain task may do so in a focused rather than global manner.

**IV.A.4. a broad range of structured didactic activities; (Core)**

**IV.A.4.a) Residents must be provided with protected time to participate in core didactic activities. (Core)**

**Background and Intent:** It is intended that residents will participate in structured didactic activities. It is recognized that there may be circumstances in which this is not possible. Programs should define core didactic activities for which time is protected and the circumstances in which residents may be excused from these didactic activities. Didactic activities may include, but are not limited to, lectures, conferences, courses, labs, asynchronous learning, simulations, drills, case discussions, grand rounds, didactic teaching, and education in critical appraisal of medical evidence.

- IV.A.5. advancement of residents' knowledge of ethical principles foundational to medical professionalism; and, (Core)
- IV.A.6. advancement in the residents' knowledge of the basic principles of scientific inquiry, including how research is designed, conducted, evaluated, explained to patients, and applied to patient care. (Core)

**IV.B. ACGME Competencies**

**Background and Intent:** The Competencies provide a conceptual framework describing the required domains for a trusted physician to enter autonomous practice. These Competencies are core to the practice of all physicians, although the specifics are further defined by each specialty. The developmental trajectories in each of the Competencies are articulated through the Milestones for each specialty.

- IV.B.1. The program must integrate the following ACGME Competencies into the curriculum: (Core)

**IV.B.1.a) Professionalism**

Residents must demonstrate a commitment to professionalism and an adherence to ethical principles. (Core)

**IV.B.1.a).(1) Residents must demonstrate competence in:**

- IV.B.1.a).(1).(a) compassion, integrity, and respect for others; (Core)

- IV.B.1.a).(1).(b) responsiveness to patient needs that supersedes self-interest; (Core)

**Background and Intent:** This includes the recognition that under certain circumstances, the interests of the patient may be best served by transitioning care to another provider. Examples include fatigue, conflict or duality of interest, not connecting well with a patient, or when another physician would be better for the situation based on skill set or knowledge base.

- IV.B.1.a).(1).(c) respect for patient privacy and autonomy; (Core)

- IV.B.1.a).(1).(d) accountability to patients, society, and the profession; (Core)

- IV.B.1.a).(1).(e) respect and responsiveness to diverse patient populations, including but not limited to diversity in gender, age, culture, race, religion, disabilities, national origin, socioeconomic status, and sexual orientation; <sup>(Core)</sup>
- IV.B.1.a).(1).(f) ability to recognize and develop a plan for one's own personal and professional well-being; and, <sup>(Core)</sup>
- IV.B.1.a).(1).(g) appropriately disclosing and addressing conflict or duality of interest. <sup>(Core)</sup>

**IV.B.1.b) Patient Care and Procedural Skills**

**Background and Intent:** Quality patient care is safe, effective, timely, efficient, patient-centered, equitable, and designed to improve population health, while reducing per capita costs. (See the Institute of Medicine [IOM]'s *Crossing the Quality Chasm: A New Health System for the 21st Century*, 2001 and Berwick D, Nolan T, Whittington J. *The Triple Aim: care, cost, and quality*. *Health Affairs*. 2008; 27(3):759-769.). In addition, there should be a focus on improving the clinician's well-being as a means to improve patient care and reduce burnout among residents, fellows, and practicing physicians.

These organizing principles inform the Common Program Requirements across all Competency domains. Specific content is determined by the Review Committees with input from the appropriate professional societies, certifying boards, and the community.

- IV.B.1.b).(1) Residents must be able to provide patient care that is compassionate, appropriate, and effective for the treatment of health problems and the promotion of health. <sup>(Core)</sup>
- IV.B.1.b).(1).(a) Residents must develop and ultimately demonstrate the ability to manage patients:
- IV.B.1.b).(1).(a).(i) in the medical and surgical care of the female reproductive system and associated disorders, and as the primary physician of women; <sup>(Core)</sup>
- IV.B.1.b).(1).(a).(ii) in a variety of roles within health systems, with progressive responsibility to include serving as the direct provider, the leader or member of a multi-disciplinary team of providers, a consultant to other physicians, and an educational resource to the patient and other members of the health care team; and, <sup>(Core)</sup>

IV.B.1.b).(1).(a).(iii) in a variety of health care settings to include the inpatient unit, labor and delivery, operating room, critical care units, and emergency and ambulatory settings. <sup>(Core)</sup>

IV.B.1.b).(2) **Residents must be able to perform all medical, diagnostic, and surgical procedures considered essential for the area of practice.** <sup>(Core)</sup>

IV.B.1.b).(2).(a) Residents must develop and ultimately demonstrate proficiency in obstetric and gynecologic procedures essential for specialty board certification. <sup>(Core)</sup>

#### IV.B.1.c) **Medical Knowledge**

**Residents must demonstrate knowledge of established and evolving biomedical, clinical, epidemiological and social-behavioral sciences, as well as the application of this knowledge to patient care.** <sup>(Core)</sup>

IV.B.1.c).(1) Resident must develop and ultimately demonstrate knowledge of the core and subspecialty content of obstetrics and gynecology, and topics related to women's health care appropriate for the unsupervised practice of obstetrics and gynecology. <sup>(Core)</sup>

#### IV.B.1.d) **Practice-based Learning and Improvement**

**Residents must demonstrate the ability to investigate and evaluate their care of patients, to appraise and assimilate scientific evidence, and to continuously improve patient care based on constant self-evaluation and lifelong learning.** <sup>(Core)</sup>

**Background and Intent: Practice-based learning and improvement is one of the defining characteristics of being a physician. It is the ability to investigate and evaluate the care of patients, to appraise and assimilate scientific evidence, and to continuously improve patient care based on constant self-evaluation and lifelong learning.**

**The intention of this Competency is to help a physician develop the habits of mind required to continuously pursue quality improvement, well past the completion of residency.**

IV.B.1.d).(1) **Residents must demonstrate competence in:**

IV.B.1.d).(1).(a) **identifying strengths, deficiencies, and limits in one's knowledge and expertise;** <sup>(Core)</sup>

IV.B.1.d).(1).(b) **setting learning and improvement goals;** <sup>(Core)</sup>



- IV.B.1.d).(1).(c) identifying and performing appropriate learning activities; <sup>(Core)</sup>
- IV.B.1.d).(1).(d) systematically analyzing practice using quality improvement methods, and implementing changes with the goal of practice improvement; <sup>(Core)</sup>
- IV.B.1.d).(1).(e) incorporating feedback and formative evaluation into daily practice; <sup>(Core)</sup>
- IV.B.1.d).(1).(f) locating, appraising, and assimilating evidence from scientific studies related to their patients' health problems; and, <sup>(Core)</sup>
- IV.B.1.d).(1).(g) using information technology to optimize learning. <sup>(Core)</sup>
- IV.B.1.e) **Interpersonal and Communication Skills**
- Residents must demonstrate interpersonal and communication skills that result in the effective exchange of information and collaboration with patients, their families, and health professionals. <sup>(Core)</sup>
- IV.B.1.e).(1) Residents must demonstrate competence in:
- IV.B.1.e).(1).(a) communicating effectively with patients, families, and the public, as appropriate, across a broad range of socioeconomic and cultural backgrounds; <sup>(Core)</sup>
- IV.B.1.e).(1).(b) communicating effectively with physicians, other health professionals, and health-related agencies; <sup>(Core)</sup>
- IV.B.1.e).(1).(c) working effectively as a member or leader of a health care team or other professional group; <sup>(Core)</sup>
- IV.B.1.e).(1).(d) educating patients, families, students, residents, and other health professionals; <sup>(Core)</sup>
- IV.B.1.e).(1).(e) acting in a consultative role to other physicians and health professionals; <sup>(Core)</sup>
- IV.B.1.e).(1).(f) maintaining comprehensive, timely, and legible medical records, if applicable; <sup>(Core)</sup>



IV.B.1.e).(1).(g) providing counseling, engaging in shared decision making, and obtaining informed consent for procedures, including the alternatives, risks, benefits, complications, and peri-operative course of those procedures; and, <sup>(Core)</sup>

IV.B.1.e).(1).(h) discussing adverse events. <sup>(Core)</sup>

IV.B.1.e).(2) **Residents must learn to communicate with patients and families to partner with them to assess their care goals, including, when appropriate, end-of-life goals.** <sup>(Core)</sup>

**Background and Intent: When there are no more medications or interventions that can achieve a patient's goals or provide meaningful improvements in quality or length of life, a discussion about the patient's goals, values, and choices surrounding the end of life is one of the most important conversations that can occur. Residents must learn to participate effectively and compassionately in these meaningful human interactions, for the sake of their patients and themselves.**

**Programs may teach this skill through direct clinical experience, simulation, or other means of active learning.**

IV.B.1.f) **Systems-based Practice**

**Residents must demonstrate an awareness of and responsiveness to the larger context and system of health care, including the social determinants of health, as well as the ability to call effectively on other resources to provide optimal health care.** <sup>(Core)</sup>

IV.B.1.f).(1) **Residents must demonstrate competence in:**

IV.B.1.f).(1).(a) **working effectively in various health care delivery settings and systems relevant to their clinical specialty;** <sup>(Core)</sup>

**Background and Intent: Medical practice occurs in the context of an increasingly complex clinical care environment where optimal patient care requires attention to compliance with external and internal administrative and regulatory requirements.**

IV.B.1.f).(1).(b) **coordinating patient care across the health care continuum and beyond as relevant to their clinical specialty;** <sup>(Core)</sup>

**Background and Intent: Every patient deserves to be treated as a whole person. Therefore it is recognized that any one component of the health care system does not meet the totality of the patient's needs. An appropriate transition plan requires coordination and forethought by an interdisciplinary team. The patient benefits from proper care and the system benefits from proper use of resources.**

- IV.B.1.f).(1).(c) **advocating for quality patient care and optimal patient care systems;** <sup>(Core)</sup>
- IV.B.1.f).(1).(d) **working in interprofessional teams to enhance patient safety and improve patient care quality;** <sup>(Core)</sup>
- IV.B.1.f).(1).(e) **participating in identifying system errors and implementing potential systems solutions;** <sup>(Core)</sup>
- IV.B.1.f).(1).(f) **incorporating considerations of value, cost awareness, delivery and payment, and risk-benefit analysis in patient and/or population-based care as appropriate; and,** <sup>(Core)</sup>
- IV.B.1.f).(1).(g) **understanding health care finances and its impact on individual patients' health decisions.** <sup>(Core)</sup>

- IV.B.1.f).(2) **Residents must learn to advocate for patients within the health care system to achieve the patient's and family's care goals, including, when appropriate, end-of-life goals.** <sup>(Core)</sup>

#### **IV.C. Curriculum Organization and Resident Experiences**

- IV.C.1. **The curriculum must be structured to optimize resident educational experiences, the length of these experiences, and supervisory continuity.** <sup>(Core)</sup>

- IV.C.1.a) Assignment of rotations must be structured to minimize the frequency of rotational transitions, and rotations must be of sufficient length to provide a quality educational experience, defined by continuity of patient care, ongoing supervision, longitudinal relationships with faculty members, and meaningful assessment and feedback. <sup>(Core)</sup>
- IV.C.1.b) Clinical experiences should be structured to facilitate learning in a manner that allows the residents to function as part of an effective interprofessional team that works together towards the shared goals of patient safety and quality improvement. <sup>(Core)</sup>
- IV.C.1.c) Programs must have schedules that minimize conflicting inpatient and outpatient responsibilities. <sup>(Core)</sup>

**Background and Intent: In some specialties, frequent rotational transitions, inadequate continuity of faculty member supervision, and dispersed patient locations within the hospital have adversely affected optimal resident education and effective team-based care. The need for patient care continuity varies from specialty to**

**specialty and by clinical situation, and may be addressed by the individual Review Committee.**

- IV.C.2. The program must provide instruction and experience in pain management if applicable for the specialty, including recognition of the signs of substance use disorder.** <sup>(Core)</sup>
- IV.C.3.** An educational program in obstetrics and gynecology must provide an opportunity for resident physicians to achieve the knowledge, skills, and attitudes essential to the practice of obstetrics and gynecology and ambulatory health care for women. The program must provide opportunity for increasing responsibility, appropriate supervision, formal instruction, critical evaluation, and feedback for residents. <sup>(Core)</sup>
- IV.C.4. Chief Resident Experience**
- IV.C.4.a)** Within the final 24 months of education, residents must serve at least 12 months as a chief resident. <sup>(Core)</sup>
- IV.C.4.b)** The clinical and academic experience as a chief resident should be structured to prepare the resident for an independent practice of obstetrics and gynecology. This chief resident experience, with appropriate supervision, should promote a high level of responsibility and independence, and should include development of technical competence and proficiency in the management of patients with complex gynecological conditions, management of complicated pregnancies, and the performance of advanced procedures. <sup>(Core)</sup>
- IV.C.5. Ambulatory Care Experience**
- IV.C.5.a)** Continuity of care is a recognized core value of the specialty of obstetrics and gynecology and must be a priority in each program. <sup>(Core)</sup>
- IV.C.5.b)** Resident experience in the provision of ambulatory care must be structured to include a minimum of 120 distinct half-day sessions over the course of the program. <sup>(Core)</sup>
- IV.C.5.c)** Each resident's ambulatory care experience must include:
- IV.C.5.c).(1)** continuity clinics, and/or maternal-fetal medicine clinics, and/or gynecologic clinics that provide appropriate continuity of patient care; <sup>(Core)</sup>
- IV.C.5.c).(1).(a)** Clinics must include a panel of patients cared for by individual residents or a team of residents. <sup>(Core)</sup>
- IV.C.5.c).(1).(b)** The distance between residents' ambulatory care assignment(s) and concurrent rotation(s) should not be so great as to impede residents' ability to easily

travel between these educational experiences. (Core)

IV.C.5.c).(2) sufficient experiences to allow residents to learn to address acute problems and follow them to resolution, and to stabilize chronic problems; (Core)

IV.C.5.c).(3) evaluation of performance data for the resident's patients relating to problem-oriented and preventive health care; (Core)

IV.C.5.c).(4) resident participation in coordination of care within and across hospital-based and outpatient health care settings; and, (Core)

IV.C.5.c).(5) availability to participate in the management of their continuity patients between outpatient visits. (Core)

IV.C.5.c).(5).(a) There must be systems of care to provide coverage of urgent problems when a resident is not readily available. (Core)

#### IV.C.6. Procedural Experience

IV.C.6.a) Residents' procedural experience must include appropriate involvement in the selection of the surgical or therapeutic option, pre-operative assessment, and post-operative care. (Core)

IV.C.6.b) Each graduating resident must perform the minimum number of cases as established by the Review Committee. (Outcome)

IV.C.6.b).(1) Performance of the minimum number of cases by a graduating resident must not be interpreted as equivalent to the achievement of competence. (Core)

#### IV.C.6.c) PGY-1 Gynecology Experiences

IV.C.6.c).(1) PGY-1 residents must have formal training in basic surgical skills, which may be provided longitudinally or as a dedicated rotation. The basic surgical skill curriculum must teach: (Core)

IV.C.6.c).(1).(a) basic operative skills, including incision management, soft tissue management, and suturing; and, (Core)

IV.C.6.c).(1).(b) the fundamentals of endoscopic surgical equipment, and safe use of electrosurgical equipment. (Core)

**Specialty-Specific Background and Intent:** The basic surgical skills curriculum during the PGY-1 is expected to provide a foundation for skills training in subsequent PGYs and prepare residents to participate in major gynecologic surgery cases in PGY-2.

IV.C.7. Family Planning

- IV.C.7.a) Programs must provide didactic activities and clinical experience in comprehensive family planning training or access to training in the provision of abortions, and this must be part of the planned curriculum. <sup>(Core)</sup>
- IV.C.7.a).(1) Residents must have didactic activities and clinical experience in all forms of contraception. <sup>(Core)</sup> [Moved from IV.C.7.d)]
- IV.C.7.a).(2) ~~Programs must ensure residents' clinical experience includes involvement~~ Residents must be involved in educating patients on the surgical and medical therapeutic ~~options methods~~ related to the provision of abortions. <sup>(Core)</sup>
- IV.C.7.a).(3) Residents must participate in the management of complications of abortions. <sup>(Core)</sup>
- IV.C.7.a).(4) Programs must provide clinical experience or access to clinical experience in the provision of abortions as part of the planned curriculum. If a program is in a jurisdiction where resident access to this clinical experience is unlawful, the program must provide access to this clinical experience in a different jurisdiction where it is lawful. <sup>(Core)</sup>
- IV.C.7.a).(4).(a) Residents who have a religious or moral objection may opt out and must not be required to participate in training in or performing induced abortions. <sup>(Core)</sup> [Moved from IV.C.7.b)]
- IV.C.7.a).(4).(b) For programs that must provide residents with this clinical experience in a different jurisdiction due to induced abortion being unlawful in the jurisdiction of the program, support must be provided for this experience by the program, in partnership with the Sponsoring Institution. <sup>(Core)</sup>

**Specialty-Specific Background and Intent:** Comprehensive family planning is an essential part of obstetrics and gynecology. For decades, the obstetrics and gynecology residency Program Requirements have included the requirement that programs provide access to induced abortion training as part of the planned curriculum. This requirement is accompanied by a related requirement that programs must allow residents with moral or religious objections to opt out of the experience.

This requirement is based on the knowledge, skills, and abilities necessary for an

obstetrician-gynecologist to practice comprehensive reproductive health care in the United States. Such training is directly relevant to preserving the life and health of pregnant patients in some instances and equips residents with the skills and knowledge necessary for providing care in other reproductive health care contexts, including but not limited to, the ability to safely evacuate the uterus in the first and second trimesters in various clinical scenarios, such as spontaneous abortion (miscarriage) and its complications. Training in abortion also addresses many generally applicable skills, including managing pain for obstetrics and gynecology procedures; providing pregnant patients evidence-based, time-sensitive care and education related to preventing severe maternal morbidity and mortality; and providing care for complications arising from unlicensed procedures involving pregnancies.

Programs must have a curriculum that includes experience in induced abortions. Programs must be structured such that residents may "opt out" rather than needing to "opt in" to this experience. Programs must allow those residents who do not desire to participate in the provision of induced abortions to "opt out" of the induced abortion clinical experience. Even if no residents have participated in the induced abortion experience, the Review Committee would consider a program with an "opt-out" curriculum to be in substantial compliance with the requirements. If a program does not have a specific family planning curriculum that includes experience in induced abortions unless it is requested by a resident, a program would be considered to have an "opt-in" curriculum, and the Review Committee would find this program to be non-compliant with these requirements.

Obstetrics and gynecology residency programs may be located in jurisdictions where induced abortions are unlawful. Residents who do not opt out of clinical training in induced abortion must receive support to obtain clinical experience in induced abortion in another jurisdiction. Depending on the circumstances, support may require financial, logistical, educational, and/or other resources. If a program, in partnership with its Sponsoring Institution, fails to provide support for this clinical experience or penalizes residents who receive such support, the program will be considered non-compliant with the requirement.

- IV.C.8. Residents must have didactic activities and clinical experience in the comprehensive management of spontaneous abortion and pregnancy loss, including patient education, expectant management, medication management, uterine evacuation, complication management, and post-pregnancy loss care. (Core)
- IV.C.8.a) Residents' clinical experience in uterine evacuation should take place in the operating room and in outpatient settings. (Core)
- IV.C.9. Didactic Education
- IV.C.10. Educational sessions in obstetrics and gynecology must be structured and regularly scheduled and held. (Core)
- IV.C.10.a) These sessions must consist of clinical teaching rounds, case conferences, simulation training, journal clubs, and protected time for educational activities covering all aspects of obstetrics and gynecology, including basic sciences pertinent to the specialty. (Core)
- IV.C.10.b) Interdisciplinary and interprofessional sessions must occur. (Core)



- IV.C.10.c) Educational sessions in racial and ethnic health disparities must be held and include disparate maternal morbidity and mortality causes and prevention, and impact of social determinants of health and understanding of racism, privilege, and bias. (Core)

#### IV.D. Scholarship

*Medicine is both an art and a science. The physician is a humanistic scientist who cares for patients. This requires the ability to think critically, evaluate the literature, appropriately assimilate new knowledge, and practice lifelong learning. The program and faculty must create an environment that fosters the acquisition of such skills through resident participation in scholarly activities. Scholarly activities may include discovery, integration, application, and teaching.*

*The ACGME recognizes the diversity of residencies and anticipates that programs prepare physicians for a variety of roles, including clinicians, scientists, and educators. It is expected that the program's scholarship will reflect its mission(s) and aims, and the needs of the community it serves. For example, some programs may concentrate their scholarly activity on quality improvement, population health, and/or teaching, while other programs might choose to utilize more classic forms of biomedical research as the focus for scholarship.*

#### IV.D.1. Program Responsibilities

- IV.D.1.a) The program must demonstrate evidence of scholarly activities consistent with its mission(s) and aims. (Core)
- IV.D.1.b) The program, in partnership with its Sponsoring Institution, must allocate adequate resources to facilitate resident and faculty involvement in scholarly activities. (Core)
- IV.D.1.c) The program must advance residents' knowledge and practice of the scholarly approach to evidence-based patient care. (Core)

**Background and Intent:** The scholarly approach can be defined as a synthesis of teaching, learning, and research with the aim of encouraging curiosity and critical thinking based on an understanding of physiology, pathophysiology, differential diagnosis, treatments, treatment alternatives, efficiency of care, and patient safety. While some faculty members are responsible for fulfilling the traditional elements of scholarship through research, integration, and teaching, all faculty members are responsible for advancing residents' scholarly approach to patient care.

**Elements of a scholarly approach to patient care include:**

- Asking meaningful questions to stimulate residents to utilize learning resources to create a differential diagnosis, a diagnostic algorithm, and treatment plan
- Challenging the evidence that the residents use to reach their medical decisions so that they understand the benefits and limits of the medical literature

- When appropriate, dissemination of scholarly learning in a peer-reviewed manner (publication or presentation)
- Improving resident learning by encouraging them to teach using a scholarly approach

The scholarly approach to patient care begins with curiosity, is grounded in the principles of evidence-based medicine, expands the knowledge base through dissemination, and develops the habits of lifelong learning by encouraging residents to be scholarly teachers.

#### **IV.D.2. Faculty Scholarly Activity**

**IV.D.2.a) Among their scholarly activity, programs must demonstrate accomplishments in at least three of the following domains:**  
(Core)

- Research in basic science, education, translational science, patient care, or population health
- Peer-reviewed grants
- Quality improvement and/or patient safety initiatives
- Systematic reviews, meta-analyses, review articles, chapters in medical textbooks, or case reports
- Creation of curricula, evaluation tools, didactic educational activities, or electronic educational materials
- Contribution to professional committees, educational organizations, or editorial boards
- Innovations in education

**IV.D.2.b) The program must demonstrate dissemination of scholarly activity within and external to the program by the following methods:**

**Background and Intent:** For the purposes of education, metrics of scholarly activity represent one of the surrogates for the program's effectiveness in the creation of an environment of inquiry that advances the residents' scholarly approach to patient care. The Review Committee will evaluate the dissemination of scholarship for the program as a whole, not for individual faculty members, for a five-year interval, for both core and non-core faculty members, with the goal of assessing the effectiveness of the creation of such an environment. The ACGME recognizes that there may be differences in scholarship requirements between different specialties and between residencies and fellowships in the same specialty.

**IV.D.2.b).(1) faculty participation in grand rounds, posters, workshops, quality improvement presentations, podium presentations, grant leadership, non-peer-reviewed print/electronic resources, articles or publications, book chapters, textbooks, webinars, service on professional committees, or serving as a**



journal reviewer, journal editorial board member, or editor; (Outcome)‡

IV.D.2.b).(2) peer-reviewed publication. (Outcome)

IV.D.3. Resident Scholarly Activity

IV.D.3.a) Residents must participate in scholarship. (Core)

V. Evaluation

V.A. Resident Evaluation

V.A.1. Feedback and Evaluation

**Background and Intent:** Feedback is ongoing information provided regarding aspects of one's performance, knowledge, or understanding. The faculty empower residents to provide much of that feedback themselves in a spirit of continuous learning and self-reflection. Feedback from faculty members in the context of routine clinical care should be frequent, and need not always be formally documented.

Formative and summative evaluation have distinct definitions. Formative evaluation is *monitoring resident learning* and providing ongoing feedback that can be used by residents to improve their learning in the context of provision of patient care or other educational opportunities. More specifically, formative evaluations help:

- residents identify their strengths and weaknesses and target areas that need work
- program directors and faculty members recognize where residents are struggling and address problems immediately

Summative evaluation is *evaluating a resident's learning* by comparing the residents against the goals and objectives of the rotation and program, respectively. Summative evaluation is utilized to make decisions about promotion to the next level of training, or program completion.

End-of-rotation and end-of-year evaluations have both summative and formative components. Information from a summative evaluation can be used formatively when residents or faculty members use it to guide their efforts and activities in subsequent rotations and to successfully complete the residency program.

Feedback, formative evaluation, and summative evaluation compare intentions with accomplishments, enabling the transformation of a neophyte physician to one with growing expertise.

V.A.1.a) Faculty members must directly observe, evaluate, and frequently provide feedback on resident performance during each rotation or similar educational assignment. (Core)

**Background and Intent:** Faculty members should provide feedback frequently throughout the course of each rotation. Residents require feedback from faculty

members to reinforce well-performed duties and tasks, as well as to correct deficiencies. This feedback will allow for the development of the learner as they strive to achieve the Milestones. More frequent feedback is strongly encouraged for residents who have deficiencies that may result in a poor final rotation evaluation.

- V.A.1.b)** Evaluation must be documented at the completion of the assignment. <sup>(Core)</sup>
- V.A.1.b).(1)** For block rotations of greater than three months in duration, evaluation must be documented at least every three months. <sup>(Core)</sup>
- V.A.1.b).(2)** Longitudinal experiences, such as continuity clinic in the context of other clinical responsibilities, must be evaluated at least every three months and at completion. <sup>(Core)</sup>
- V.A.1.c)** The program must provide an objective performance evaluation based on the Competencies and the specialty-specific Milestones, and must: <sup>(Core)</sup>
- V.A.1.c).(1)** use multiple evaluators (e.g., faculty members, peers, patients, self, and other professional staff members); and, <sup>(Core)</sup>
- V.A.1.c).(2)** provide that information to the Clinical Competency Committee for its synthesis of progressive resident performance and improvement toward unsupervised practice. <sup>(Core)</sup>
- V.A.1.d)** The program director or their designee, with input from the Clinical Competency Committee, must:
- V.A.1.d).(1)** meet with and review with each resident their documented semi-annual evaluation of performance, including progress along the specialty-specific Milestones; <sup>(Core)</sup>
- V.A.1.d).(1).(a)** The semiannual evaluation must include review, with each resident, of progress along the Milestone continuum and of the record of operative experience to ensure breadth and depth of experience and continuing growth in technical and clinical competence. <sup>(Core)</sup>
- V.A.1.d).(2)** assist residents in developing individualized learning plans to capitalize on their strengths and identify areas for growth; and, <sup>(Core)</sup>
- V.A.1.d).(3)** develop plans for residents failing to progress, following institutional policies and procedures. <sup>(Core)</sup>

**Background and Intent:** Learning is an active process that requires effort from the teacher and the learner. Faculty members evaluate a resident's performance at least at the end of each rotation. The program director or their designee will review those evaluations, including their progress on the Milestones, at a minimum of every six months. Residents should be encouraged to reflect upon the evaluation, using the information to reinforce well-performed tasks or knowledge or to modify deficiencies in knowledge or practice. Working together with the faculty members, residents should develop an individualized learning plan.

Residents who are experiencing difficulties with achieving progress along the Milestones may require intervention to address specific deficiencies. Such intervention, documented in an individual remediation plan developed by the program director or a faculty mentor and the resident, will take a variety of forms based on the specific learning needs of the resident. However, the ACGME recognizes that there are situations which require more significant intervention that may alter the time course of resident progression. To ensure due process, it is essential that the program director follow institutional policies and procedures.

- V.A.1.e)** At least annually, there must be a summative evaluation of each resident that includes their readiness to progress to the next year of the program, if applicable. (Core)
- V.A.1.f)** The evaluations of a resident's performance must be accessible for review by the resident. (Core)
- V.A.1.g)** Assessment should specifically monitor the resident's knowledge by use of a formal exam such as the Council on Resident Education in Obstetrics and Gynecology (CREOG) In-Training Examination or other cognitive exams. Tests results should not be the sole criterion of resident knowledge, and should not be used as the sole criterion for promotion to a subsequent PG level. (Detail)
- V.A.2. Final Evaluation**
- V.A.2.a)** The program director must provide a final evaluation for each resident upon completion of the program. (Core)
- V.A.2.a).(1)** The specialty-specific Milestones, and when applicable the specialty-specific Case Logs, must be used as tools to ensure residents are able to engage in autonomous practice upon completion of the program. (Core)
- V.A.2.a).(2)** The final evaluation must:
- V.A.2.a).(2).(a)** become part of the resident's permanent record maintained by the institution, and must be accessible for review by the resident in accordance with institutional policy; (Core)

- V.A.2.a).(2).(b)** verify that the resident has demonstrated the knowledge, skills, and behaviors necessary to enter autonomous practice; <sup>(Core)</sup>
- V.A.2.a).(2).(c)** consider recommendations from the Clinical Competency Committee; and, <sup>(Core)</sup>
- V.A.2.a).(2).(d)** be shared with the resident upon completion of the program. <sup>(Core)</sup>
- V.A.3.** **A Clinical Competency Committee must be appointed by the program director.** <sup>(Core)</sup>
- V.A.3.a)** At a minimum, the Clinical Competency Committee must include three members of the program faculty, at least one of whom is a core faculty member. <sup>(Core)</sup>
- V.A.3.a).(1)** Additional members must be faculty members from the same program or other programs, or other health professionals who have extensive contact and experience with the program's residents. <sup>(Core)</sup>

**Background and Intent:** The requirements regarding the Clinical Competency Committee do not preclude or limit a program director's participation on the Clinical Competency Committee. The intent is to leave flexibility for each program to decide the best structure for its own circumstances, but a program should consider: its program director's other roles as resident advocate, advisor, and confidante; the impact of the program director's presence on the other Clinical Competency Committee members' discussions and decisions; the size of the program faculty; and other program-relevant factors. The program director has final responsibility for resident evaluation and promotion decisions.

Program faculty may include more than the physician faculty members, such as other physicians and non-physicians who teach and evaluate the program's residents. There may be additional members of the Clinical Competency Committee. Chief residents who have completed core residency programs in their specialty may be members of the Clinical Competency Committee.

- V.A.3.b)** **The Clinical Competency Committee must:**
- V.A.3.b).(1)** review all resident evaluations at least semi-annually; <sup>(Core)</sup>
- V.A.3.b).(2)** determine each resident's progress on achievement of the specialty-specific Milestones; and, <sup>(Core)</sup>
- V.A.3.b).(3)** meet prior to the residents' semi-annual evaluations and advise the program director regarding each resident's progress. <sup>(Core)</sup>
- V.B.** **Faculty Evaluation**

- V.B.1.** The program must have a process to evaluate each faculty member's performance as it relates to the educational program at least annually. <sup>(Core)</sup>

**Background and Intent:** The program director is responsible for the education program and for whom delivers it. While the term "faculty" may be applied to physicians within a given institution for other reasons, it is applied to residency program faculty members only through approval by a program director. The development of the faculty improves the education, clinical, and research aspects of a program. Faculty members have a strong commitment to the resident and desire to provide optimal education and work opportunities. Faculty members must be provided feedback on their contribution to the mission of the program. All faculty members who interact with residents desire feedback on their education, clinical care, and research. If a faculty member does not interact with residents, feedback is not required. With regard to the diverse operating environments and configurations, the residency program director may need to work with others to determine the effectiveness of the program's faculty performance with regard to their role in the educational program. All teaching faculty members should have their educational efforts evaluated by the residents in a confidential and anonymous manner. Other aspects for the feedback may include research or clinical productivity, review of patient outcomes, or peer review of scholarly activity. The process should reflect the local environment and identify the necessary information. The feedback from the various sources should be summarized and provided to the faculty on an annual basis by a member of the leadership team of the program.

- V.B.1.a)** This evaluation must include a review of the faculty member's clinical teaching abilities, engagement with the educational program, participation in faculty development related to their skills as an educator, clinical performance, professionalism, and scholarly activities. <sup>(Core)</sup>
- V.B.1.b)** This evaluation must include written, anonymous, and confidential evaluations by the residents. <sup>(Core)</sup>
- V.B.2.** Faculty members must receive feedback on their evaluations at least annually. <sup>(Core)</sup>
- V.B.3.** Results of the faculty educational evaluations should be incorporated into program-wide faculty development plans. <sup>(Core)</sup>

**Background and Intent:** The quality of the faculty's teaching and clinical care is a determinant of the quality of the program and the quality of the residents' future clinical care. Therefore, the program has the responsibility to evaluate and improve the program faculty members' teaching, scholarship, professionalism, and quality care. This section mandates annual review of the program's faculty members for this purpose, and can be used as input into the Annual Program Evaluation.

**V.C. Program Evaluation and Improvement**

- V.C.1.** The program director must appoint the Program Evaluation Committee to conduct and document the Annual Program

**Evaluation as part of the program's continuous improvement process.** <sup>(Core)</sup>

- V.C.1.a)**                      **The Program Evaluation Committee must be composed of at least two program faculty members, at least one of whom is a core faculty member, and at least one resident.** <sup>(Core)</sup>
- V.C.1.b)**                      **Program Evaluation Committee responsibilities must include:**
- V.C.1.b).(1)**                      **acting as an advisor to the program director, through program oversight;** <sup>(Core)</sup>
- V.C.1.b).(2)**                      **review of the program's self-determined goals and progress toward meeting them;** <sup>(Core)</sup>
- V.C.1.b).(3)**                      **guiding ongoing program improvement, including development of new goals, based upon outcomes; and,** <sup>(Core)</sup>
- V.C.1.b).(4)**                      **review of the current operating environment to identify strengths, challenges, opportunities, and threats as related to the program's mission and aims.** <sup>(Core)</sup>

**Background and Intent:** In order to achieve its mission and train quality physicians, a program must evaluate its performance and plan for improvement in the Annual Program Evaluation. Performance of residents and faculty members is a reflection of program quality, and can use metrics that reflect the goals that a program has set for itself. The Program Evaluation Committee utilizes outcome parameters and other data to assess the program's progress toward achievement of its goals and aims.

- V.C.1.c)**                      **The Program Evaluation Committee should consider the following elements in its assessment of the program:**
- V.C.1.c).(1)**                      **curriculum;** <sup>(Core)</sup>
- V.C.1.c).(2)**                      **outcomes from prior Annual Program Evaluation(s);** <sup>(Core)</sup>
- V.C.1.c).(3)**                      **ACGME letters of notification, including citations, Areas for Improvement, and comments;** <sup>(Core)</sup>
- V.C.1.c).(4)**                      **quality and safety of patient care;** <sup>(Core)</sup>
- V.C.1.c).(5)**                      **aggregate resident and faculty:**
- V.C.1.c).(5).(a)**                      **well-being;** <sup>(Core)</sup>
- V.C.1.c).(5).(b)**                      **recruitment and retention;** <sup>(Core)</sup>
- V.C.1.c).(5).(c)**                      **workforce diversity;** <sup>(Core)</sup>

- V.C.1.c).(5).(d) engagement in quality improvement and patient safety; <sup>(Core)</sup>
- V.C.1.c).(5).(e) scholarly activity; <sup>(Core)</sup>
- V.C.1.c).(5).(f) ACGME Resident and Faculty Surveys; and, <sup>(Core)</sup>
- V.C.1.c).(5).(g) written evaluations of the program. <sup>(Core)</sup>
- V.C.1.c).(6) aggregate resident:
- V.C.1.c).(6).(a) achievement of the Milestones; <sup>(Core)</sup>
- V.C.1.c).(6).(b) in-training examinations (where applicable); <sup>(Core)</sup>
- V.C.1.c).(6).(c) board pass and certification rates; and, <sup>(Core)</sup>
- V.C.1.c).(6).(d) graduate performance. <sup>(Core)</sup>
- V.C.1.c).(7) aggregate faculty:
- V.C.1.c).(7).(a) evaluation; and, <sup>(Core)</sup>
- V.C.1.c).(7).(b) professional development. <sup>(Core)</sup>
- V.C.1.d) The Program Evaluation Committee must evaluate the program's mission and aims, strengths, areas for improvement, and threats. <sup>(Core)</sup>
- V.C.1.e) The annual review, including the action plan, must:
- V.C.1.e).(1) be distributed to and discussed with the members of the teaching faculty and the residents; and, <sup>(Core)</sup>
- V.C.1.e).(2) be submitted to the DIO. <sup>(Core)</sup>
- V.C.2. The program must complete a Self-Study prior to its 10-Year Accreditation Site Visit. <sup>(Core)</sup>
- V.C.2.a) A summary of the Self-Study must be submitted to the DIO. <sup>(Core)</sup>

**Background and Intent: Outcomes of the documented Annual Program Evaluation can be integrated into the 10-year Self-Study process. The Self-Study is an objective, comprehensive evaluation of the residency program, with the aim of improving it. Underlying the Self-Study is this longitudinal evaluation of the program and its learning environment, facilitated through sequential Annual Program Evaluations that focus on the required components, with an emphasis on program strengths and self-identified areas for improvement. Details regarding the timing and expectations for the**



Self-Study and the 10-Year Accreditation Site Visit are provided in the *ACGME Manual of Policies and Procedures*. Additionally, a description of the [Self-Study process](#), as well as information on how to prepare for the [10-Year Accreditation Site Visit](#), is available on the ACGME website.

- V.C.3.** *One goal of ACGME-accredited education is to educate physicians who seek and achieve board certification. One measure of the effectiveness of the educational program is the ultimate pass rate.*
- The program director should encourage all eligible program graduates to take the certifying examination offered by the applicable American Board of Medical Specialties (ABMS) member board or American Osteopathic Association (AOA) certifying board.*
- V.C.3.a)** For specialties in which the ABMS member board and/or AOA certifying board offer(s) an annual written exam, in the preceding three years, the program's aggregate pass rate of those taking the examination for the first time must be higher than the bottom fifth percentile of programs in that specialty.  
(Outcome)
- V.C.3.b)** For specialties in which the ABMS member board and/or AOA certifying board offer(s) a biennial written exam, in the preceding six years, the program's aggregate pass rate of those taking the examination for the first time must be higher than the bottom fifth percentile of programs in that specialty.  
(Outcome)
- V.C.3.c)** For specialties in which the ABMS member board and/or AOA certifying board offer(s) an annual oral exam, in the preceding three years, the program's aggregate pass rate of those taking the examination for the first time must be higher than the bottom fifth percentile of programs in that specialty.  
(Outcome)
- V.C.3.d)** For specialties in which the ABMS member board and/or AOA certifying board offer(s) a biennial oral exam, in the preceding six years, the program's aggregate pass rate of those taking the examination for the first time must be higher than the bottom fifth percentile of programs in that specialty. (Outcome)
- V.C.3.e)** For each of the exams referenced in V.C.3.a)-d), any program whose graduates over the time period specified in the requirement have achieved an 80 percent pass rate will have met this requirement, no matter the percentile rank of the program for pass rate in that specialty. (Outcome)

**Background and Intent:** Setting a single standard for pass rate that works across specialties is not supportable based on the heterogeneity of the psychometrics of different examinations. By using a percentile rank, the performance of the lower five

percent (fifth percentile) of programs can be identified and set on a path to curricular and test preparation reform.

There are specialties where there is a very high board pass rate that could leave successful programs in the bottom five percent (fifth percentile) despite admirable performance. These high-performing programs should not be cited, and V.C.3.e) is designed to address this.

**V.C.3.f)**

Programs must report, in ADS, board certification status annually for the cohort of board-eligible residents that graduated seven years earlier. <sup>(Core)</sup>

**Background and Intent:** It is essential that residency programs demonstrate knowledge and skill transfer to their residents. One measure of that is the qualifying or initial certification exam pass rate. Another important parameter of the success of the program is the ultimate board certification rate of its graduates. Graduates are eligible for up to seven years from residency graduation for initial certification. The ACGME will calculate a rolling three-year average of the ultimate board certification rate at seven years post-graduation, and the Review Committees will monitor it.

The Review Committees will track the rolling seven-year certification rate as an indicator of program quality. Programs are encouraged to monitor their graduates' performance on board certification examinations.

In the future, the ACGME may establish parameters related to ultimate board certification rates.

**VI. The Learning and Working Environment**

*Residency education must occur in the context of a learning and working environment that emphasizes the following principles:*

- *Excellence in the safety and quality of care rendered to patients by residents today*
- *Excellence in the safety and quality of care rendered to patients by today's residents in their future practice*
- *Excellence in professionalism through faculty modeling of:*
  - *the effacement of self-interest in a humanistic environment that supports the professional development of physicians*
  - *the joy of curiosity, problem-solving, intellectual rigor, and discovery*
- *Commitment to the well-being of the students, residents, faculty members, and all members of the health care team*

**Background and Intent:** The revised requirements are intended to provide greater flexibility within an established framework, allowing programs and residents more

discretion to structure clinical education in a way that best supports the above principles of professional development. With this increased flexibility comes the responsibility for programs and residents to adhere to the 80-hour maximum weekly limit (unless a rotation-specific exception is granted by a Review Committee), and to utilize flexibility in a manner that optimizes patient safety, resident education, and resident well-being. The requirements are intended to support the development of a sense of professionalism by encouraging residents to make decisions based on patient needs and their own well-being, without fear of jeopardizing their program's accreditation status. In addition, the proposed requirements eliminate the burdensome documentation requirement for residents to justify clinical and educational work hour variations.

Clinical and educational work hours represent only one part of the larger issue of conditions of the learning and working environment, and Section VI has now been expanded to include greater attention to patient safety and resident and faculty member well-being. The requirements are intended to support programs and residents as they strive for excellence, while also ensuring ethical, humanistic training. Ensuring that flexibility is used in an appropriate manner is a shared responsibility of the program and residents. With this flexibility comes a responsibility for residents and faculty members to recognize the need to hand off care of a patient to another provider when a resident is too fatigued to provide safe, high quality care and for programs to ensure that residents remain within the 80-hour maximum weekly limit.

#### **VI.A. Patient Safety, Quality Improvement, Supervision, and Accountability**

##### **VI.A.1. Patient Safety and Quality Improvement**

*All physicians share responsibility for promoting patient safety and enhancing quality of patient care. Graduate medical education must prepare residents to provide the highest level of clinical care with continuous focus on the safety, individual needs, and humanity of their patients. It is the right of each patient to be cared for by residents who are appropriately supervised; possess the requisite knowledge, skills, and abilities; understand the limits of their knowledge and experience; and seek assistance as required to provide optimal patient care.*

*Residents must demonstrate the ability to analyze the care they provide, understand their roles within health care teams, and play an active role in system improvement processes. Graduating residents will apply these skills to critique their future unsupervised practice and effect quality improvement measures.*

*It is necessary for residents and faculty members to consistently work in a well-coordinated manner with other health care professionals to achieve organizational patient safety goals.*

##### **VI.A.1.a) Patient Safety**

##### **VI.A.1.a).(1) Culture of Safety**

***A culture of safety requires continuous identification of vulnerabilities and a willingness to transparently deal with them. An effective organization has formal mechanisms to assess the knowledge, skills, and attitudes of its personnel toward safety in order to identify areas for improvement.***

**VI.A.1.a).(1).(a)** The program, its faculty, residents, and fellows must actively participate in patient safety systems and contribute to a culture of safety.  
(Core)

**VI.A.1.a).(1).(b)** The program must have a structure that promotes safe, interprofessional, team-based care. (Core)

**VI.A.1.a).(2)** Education on Patient Safety

Programs must provide formal educational activities that promote patient safety-related goals, tools, and techniques. (Core)

<p><b>Background and Intent: Optimal patient safety occurs in the setting of a coordinated interprofessional learning and working environment.</b></p>
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**VI.A.1.a).(3)** Patient Safety Events

***Reporting, investigation, and follow-up of adverse events, near misses, and unsafe conditions are pivotal mechanisms for improving patient safety, and are essential for the success of any patient safety program. Feedback and experiential learning are essential to developing true competence in the ability to identify causes and institute sustainable systems-based changes to ameliorate patient safety vulnerabilities.***

**VI.A.1.a).(3).(a)** Residents, fellows, faculty members, and other clinical staff members must:

**VI.A.1.a).(3).(a).(i)** know their responsibilities in reporting patient safety events at the clinical site;  
(Core)

**VI.A.1.a).(3).(a).(ii)** know how to report patient safety events, including near misses, at the clinical site; and, (Core)

**VI.A.1.a).(3).(a).(iii)** be provided with summary information of their institution's patient safety reports. (Core)

**VI.A.1.a).(3).(b)** Residents must participate as team members in real and/or simulated interprofessional clinical patient safety activities, such as root cause analyses or other activities that include analysis, as well as formulation and implementation of actions. <sup>(Core)</sup>

**VI.A.1.a).(4)** Resident Education and Experience in Disclosure of Adverse Events

*Patient-centered care requires patients, and when appropriate families, to be apprised of clinical situations that affect them, including adverse events. This is an important skill for faculty physicians to model, and for residents to develop and apply.*

**VI.A.1.a).(4).(a)** All residents must receive training in how to disclose adverse events to patients and families. <sup>(Core)</sup>

**VI.A.1.a).(4).(b)** Residents should have the opportunity to participate in the disclosure of patient safety events, real or simulated. <sup>(Detail)</sup>

**VI.A.1.b)** Quality Improvement

**VI.A.1.b).(1)** Education in Quality Improvement

*A cohesive model of health care includes quality-related goals, tools, and techniques that are necessary in order for health care professionals to achieve quality improvement goals.*

**VI.A.1.b).(1).(a)** Residents must receive training and experience in quality improvement processes, including an understanding of health care disparities. <sup>(Core)</sup>

**VI.A.1.b).(2)** Quality Metrics

*Access to data is essential to prioritizing activities for care improvement and evaluating success of improvement efforts.*

**VI.A.1.b).(2).(a)** Residents and faculty members must receive data on quality metrics and benchmarks related to their patient populations. <sup>(Core)</sup>

**VI.A.1.b).(3)** Engagement in Quality Improvement Activities

***Experiential learning is essential to developing the ability to identify and institute sustainable systems-based changes to improve patient care.***

**VI.A.1.b).(3).(a)**

**Residents must have the opportunity to participate in interprofessional quality improvement activities. (Core)**

**VI.A.1.b).(3).(a).(i)**

**This should include activities aimed at reducing health care disparities. (Detail)**

**VI.A.2.**

**Supervision and Accountability**

**VI.A.2.a)**

***Although the attending physician is ultimately responsible for the care of the patient, every physician shares in the responsibility and accountability for their efforts in the provision of care. Effective programs, in partnership with their Sponsoring Institutions, define, widely communicate, and monitor a structured chain of responsibility and accountability as it relates to the supervision of all patient care.***

***Supervision in the setting of graduate medical education provides safe and effective care to patients; ensures each resident's development of the skills, knowledge, and attitudes required to enter the unsupervised practice of medicine; and establishes a foundation for continued professional growth.***

**VI.A.2.a).(1)**

**Each patient must have an identifiable and appropriately-credentialed and privileged attending physician (or licensed independent practitioner as specified by the applicable Review Committee) who is responsible and accountable for the patient's care. (Core)**

**VI.A.2.a).(1).(a)**

**This information must be available to residents, faculty members, other members of the health care team, and patients. (Core)**

**VI.A.2.a).(1).(b)**

**Residents and faculty members must inform each patient of their respective roles in that patient's care when providing direct patient care. (Core)**

**VI.A.2.b)**

***Supervision may be exercised through a variety of methods. For many aspects of patient care, the supervising physician may be a more advanced resident or fellow. Other portions of care provided by the resident can be adequately supervised by the appropriate availability of the supervising faculty member, fellow, or senior resident physician, either on site or by means of telecommunication technology. Some activities***

*require the physical presence of the supervising faculty member. In some circumstances, supervision may include post-hoc review of resident-delivered care with feedback.*

**Background and Intent:** Appropriate supervision is essential for patient safety and high-quality teaching. Supervision is also contextual. There is tremendous diversity of resident patient interactions, education and training locations, and resident skills and abilities even at the same level of the educational program. The degree of supervision is expected to evolve progressively as a resident gains more experience, even with the same patient condition or procedure. All residents have a level of supervision commensurate with their level of autonomy in practice; this level of supervision may be enhanced based on factors such as patient safety, complexity, acuity, urgency, risk of serious adverse events, or other pertinent variables.

- VI.A.2.b).(1)** The program must demonstrate that the appropriate level of supervision in place for all residents is based on each resident's level of training and ability, as well as patient complexity and acuity. Supervision may be exercised through a variety of methods, as appropriate to the situation. <sup>(Core)</sup>
- VI.A.2.b).(1).(a)** Physician faculty member supervision of residents must comply with II.B.2.h)-II.B.2.h).(2). <sup>(Core)</sup>
- VI.A.2.b).(2)** The program must define when physical presence of a supervising physician is required. <sup>(Core)</sup>
- VI.A.2.c)** **Levels of Supervision**
- To promote appropriate resident supervision while providing for graded authority and responsibility, the program must use the following classification of supervision: <sup>(Core)</sup>
- VI.A.2.c).(1)** **Direct Supervision:**
- VI.A.2.c).(1).(a)** the supervising physician is physically present with the resident during the key portions of the patient interaction; or, <sup>(Core)</sup>
- VI.A.2.c).(1).(a).(i)** PGY-1 residents must initially be supervised directly, only as described in VI.A.2.c).(1).(a). <sup>(Core)</sup>
- VI.A.2.c).(1).(b)** the supervising physician and/or patient is not physically present with the resident and the supervising physician is concurrently monitoring the patient care through appropriate telecommunication technology. <sup>(Core)</sup>
- VI.A.2.c).(1).(b).(i)** Telecommunication technology for direct supervision must not be used for the



management of labor and delivery or with  
invasive procedures. <sup>(Core)</sup>

**VI.A.2.c).(2)** **Indirect Supervision: the supervising physician is not providing physical or concurrent visual or audio supervision but is immediately available to the resident for guidance and is available to provide appropriate direct supervision.** <sup>(Core)</sup>

**VI.A.2.c).(3)** **Oversight – the supervising physician is available to provide review of procedures/encounters with feedback provided after care is delivered.** <sup>(Core)</sup>

**VI.A.2.d)** **The privilege of progressive authority and responsibility, conditional independence, and a supervisory role in patient care delegated to each resident must be assigned by the program director and faculty members.** <sup>(Core)</sup>

**VI.A.2.d).(1)** **The program director must evaluate each resident's abilities based on specific criteria, guided by the Milestones.** <sup>(Core)</sup>

**VI.A.2.d).(2)** **Faculty members functioning as supervising physicians must delegate portions of care to residents based on the needs of the patient and the skills of each resident.** <sup>(Core)</sup>

**VI.A.2.d).(3)** **Senior residents or fellows should serve in a supervisory role to junior residents in recognition of their progress toward independence, based on the needs of each patient and the skills of the individual resident or fellow.** <sup>(Detail)</sup>

**VI.A.2.e)** **Programs must set guidelines for circumstances and events in which residents must communicate with the supervising faculty member(s).** <sup>(Core)</sup>

**VI.A.2.e).(1)** **Each resident must know the limits of their scope of authority, and the circumstances under which the resident is permitted to act with conditional independence.** <sup>(Outcome)</sup>

**Background and Intent: The ACGME Glossary of Terms defines conditional independence as: Graded, progressive responsibility for patient care with defined oversight.**

**VI.A.2.f)** **Faculty supervision assignments must be of sufficient duration to assess the knowledge and skills of each resident and to delegate to the resident the appropriate level of patient care authority and responsibility.** <sup>(Core)</sup>

**VI.B. Professionalism**

**VI.B.1.** Programs, in partnership with their Sponsoring Institutions, must educate residents and faculty members concerning the professional responsibilities of physicians, including their obligation to be appropriately rested and fit to provide the care required by their patients. <sup>(Core)</sup>

**VI.B.2.** The learning objectives of the program must:

**VI.B.2.a)** be accomplished through an appropriate blend of supervised patient care responsibilities, clinical teaching, and didactic educational events; <sup>(Core)</sup>

**VI.B.2.b)** be accomplished without excessive reliance on residents to fulfill non-physician obligations; and, <sup>(Core)</sup>

**Background and Intent:** Routine reliance on residents to fulfill non-physician obligations increases work compression for residents and does not provide an optimal educational experience. Non-physician obligations are those duties which in most institutions are performed by nursing and allied health professionals, transport services, or clerical staff. Examples of such obligations include transport of patients from the wards or units for procedures elsewhere in the hospital; routine blood drawing for laboratory tests; routine monitoring of patients when off the ward; and clerical duties, such as scheduling. While it is understood that residents may be expected to do any of these things on occasion when the need arises, these activities should not be performed by residents routinely and must be kept to a minimum to optimize resident education.

**VI.B.2.c)** ensure manageable patient care responsibilities. <sup>(Core)</sup>

**Background and Intent:** The Common Program Requirements do not define “manageable patient care responsibilities” as this is variable by specialty and PGY level. Review Committees will provide further detail regarding patient care responsibilities in the applicable specialty-specific Program Requirements and accompanying FAQs. However, all programs, regardless of specialty, should carefully assess how the assignment of patient care responsibilities can affect work compression, especially at the PGY-1 level.

**VI.B.3.** The program director, in partnership with the Sponsoring Institution, must provide a culture of professionalism that supports patient safety and personal responsibility. <sup>(Core)</sup>

**VI.B.4.** Residents and faculty members must demonstrate an understanding of their personal role in the:

**VI.B.4.a)** provision of patient- and family-centered care; <sup>(Outcome)</sup>

**VI.B.4.b)** safety and welfare of patients entrusted to their care, including the ability to report unsafe conditions and adverse events; <sup>(Outcome)</sup>

**Background and Intent:** This requirement emphasizes that responsibility for reporting unsafe conditions and adverse events is shared by all members of the team and is not solely the responsibility of the resident.

**VI.B.4.c)** assurance of their fitness for work, including: (Outcome)

**Background and Intent:** This requirement emphasizes the professional responsibility of faculty members and residents to arrive for work adequately rested and ready to care for patients. It is also the responsibility of faculty members, residents, and other members of the care team to be observant, to intervene, and/or to escalate their concern about resident and faculty member fitness for work, depending on the situation, and in accordance with institutional policies.

**VI.B.4.c).(1)** management of their time before, during, and after clinical assignments; and, (Outcome)

**VI.B.4.c).(2)** recognition of impairment, including from illness, fatigue, and substance use, in themselves, their peers, and other members of the health care team. (Outcome)

**VI.B.4.d)** commitment to lifelong learning; (Outcome)

**VI.B.4.e)** monitoring of their patient care performance improvement indicators; and, (Outcome)

**VI.B.4.f)** accurate reporting of clinical and educational work hours, patient outcomes, and clinical experience data. (Outcome)

**VI.B.5.** All residents and faculty members must demonstrate responsiveness to patient needs that supersedes self-interest. This includes the recognition that under certain circumstances, the best interests of the patient may be served by transitioning that patient's care to another qualified and rested provider. (Outcome)

**VI.B.6.** Programs, in partnership with their Sponsoring Institutions, must provide a professional, equitable, respectful, and civil environment that is free from discrimination, sexual and other forms of harassment, mistreatment, abuse, or coercion of students, residents, faculty, and staff. (Core)

**VI.B.7.** Programs, in partnership with their Sponsoring Institutions, should have a process for education of residents and faculty regarding unprofessional behavior and a confidential process for reporting, investigating, and addressing such concerns. (Core)

**VI.C.** Well-Being

*Psychological, emotional, and physical well-being are critical in the development of the competent, caring, and resilient physician and require*

*proactive attention to life inside and outside of medicine. Well-being requires that physicians retain the joy in medicine while managing their own real-life stresses. Self-care and responsibility to support other members of the health care team are important components of professionalism; they are also skills that must be modeled, learned, and nurtured in the context of other aspects of residency training.*

*Residents and faculty members are at risk for burnout and depression. Programs, in partnership with their Sponsoring Institutions, have the same responsibility to address well-being as other aspects of resident competence. Physicians and all members of the health care team share responsibility for the well-being of each other. For example, a culture which encourages covering for colleagues after an illness without the expectation of reciprocity reflects the ideal of professionalism. A positive culture in a clinical learning environment models constructive behaviors, and prepares residents with the skills and attitudes needed to thrive throughout their careers.*

**Background and Intent:** The ACGME is committed to addressing physician well-being for individuals and as it relates to the learning and working environment. The creation of a learning and working environment with a culture of respect and accountability for physician well-being is crucial to physicians' ability to deliver the safest, best possible care to patients. The ACGME is leveraging its resources in four key areas to support the ongoing focus on physician well-being: education, influence, research, and collaboration. Information regarding the ACGME's ongoing efforts in this area is available on the ACGME website: [www.acgme.org/physicianwellbeing](http://www.acgme.org/physicianwellbeing).

The ACGME also created a repository for well-being materials, assessments, presentations, and more on the [Well-Being Tools and Resources page](#) in Learn at ACGME for programs seeking to develop or strengthen their own well-being initiatives. There are many activities that programs can implement now to assess and support physician well-being. These include the distribution and analysis of culture of safety surveys, ensuring the availability of counseling services, and paying attention to the safety of the entire health care team.

- VI.C.1.** The responsibility of the program, in partnership with the Sponsoring Institution, to address well-being must include:
  - VI.C.1.a)** efforts to enhance the meaning that each resident finds in the experience of being a physician, including protecting time with patients, minimizing non-physician obligations, providing administrative support, promoting progressive autonomy and flexibility, and enhancing professional relationships; <sup>(Core)</sup>
  - VI.C.1.b)** attention to scheduling, work intensity, and work compression that impacts resident well-being; <sup>(Core)</sup>
  - VI.C.1.c)** evaluating workplace safety data and addressing the safety of residents and faculty members; <sup>(Core)</sup>

**Background and Intent:** This requirement emphasizes the responsibility shared by the Sponsoring Institution and its programs to gather information and utilize systems that monitor and enhance resident and faculty member safety, including physical safety. Issues to be addressed include, but are not limited to, monitoring of workplace injuries, physical or emotional violence, vehicle collisions, and emotional well-being after adverse events.

**VI.C.1.d)** policies and programs that encourage optimal resident and faculty member well-being; and, <sup>(Core)</sup>

**Background and Intent:** Well-being includes having time away from work to engage with family and friends, as well as to attend to personal needs and to one's own health, including adequate rest, healthy diet, and regular exercise.

**VI.C.1.d).(1)** Residents must be given the opportunity to attend medical, mental health, and dental care appointments, including those scheduled during their working hours. <sup>(Core)</sup>

**Background and Intent:** The intent of this requirement is to ensure that residents have the opportunity to access medical and dental care, including mental health care, at times that are appropriate to their individual circumstances. Residents must be provided with time away from the program as needed to access care, including appointments scheduled during their working hours.

**VI.C.1.e)** attention to resident and faculty member burnout, depression, and substance use disorders. The program, in partnership with its Sponsoring Institution, must educate faculty members and residents in identification of the symptoms of burnout, depression, and substance use disorders, including means to assist those who experience these conditions. Residents and faculty members must also be educated to recognize those symptoms in themselves and how to seek appropriate care. The program, in partnership with its Sponsoring Institution, must: <sup>(Core)</sup>

**Background and Intent:** Programs and Sponsoring Institutions are encouraged to review materials to create systems for identification of burnout, depression, and substance use disorders. Materials and more information are available in Learn at ACGME (<https://dl.acgme.org/pages/well-being-tools-resources>).

**VI.C.1.e).(1)** encourage residents and faculty members to alert the program director or other designated personnel or programs when they are concerned that another resident, fellow, or faculty member may be displaying signs of burnout, depression, a substance use disorder, suicidal ideation, or potential for violence; <sup>(Core)</sup>

**Background and Intent:** Individuals experiencing burnout, depression, a substance use disorder, and/or suicidal ideation are often reluctant to reach out for help due to the stigma associated with these conditions, and are concerned that seeking help may have a negative impact on their career. Recognizing that physicians are at increased risk in these areas, it is essential that residents and faculty members are able to report their concerns when another resident or faculty member displays signs of any of these conditions, so that the program director or other designated personnel, such as the department chair, may assess the situation and intervene as necessary to facilitate access to appropriate care. Residents and faculty members must know which personnel, in addition to the program director, have been designated with this responsibility; those personnel and the program director should be familiar with the institution's impaired physician policy and any employee health, employee assistance, and/or wellness programs within the institution. In cases of physician impairment, the program director or designated personnel should follow the policies of their institution for reporting.

**VI.C.1.e).(2)** provide access to appropriate tools for self-screening; and, <sup>(Core)</sup>

**VI.C.1.e).(3)** provide access to confidential, affordable mental health assessment, counseling, and treatment, including access to urgent and emergent care 24 hours a day, seven days a week. <sup>(Core)</sup>

**Background and Intent:** The intent of this requirement is to ensure that residents have immediate access at all times to a mental health professional (psychiatrist, psychologist, Licensed Clinical Social Worker, Primary Mental Health Nurse Practitioner, or Licensed Professional Counselor) for urgent or emergent mental health issues. In-person, telemedicine, or telephonic means may be utilized to satisfy this requirement. Care in the Emergency Department may be necessary in some cases, but not as the primary or sole means to meet the requirement.

The reference to affordable counseling is intended to require that financial cost not be a barrier to obtaining care.

**VI.C.2.** There are circumstances in which residents may be unable to attend work, including but not limited to fatigue, illness, family emergencies, and parental leave. Each program must allow an appropriate length of absence for residents unable to perform their patient care responsibilities. <sup>(Core)</sup>

**VI.C.2.a)** The program must have policies and procedures in place to ensure coverage of patient care. <sup>(Core)</sup>

**VI.C.2.b)** These policies must be implemented without fear of negative consequences for the resident who is or was unable to provide the clinical work. <sup>(Core)</sup>

**Background and Intent:** Residents may need to extend their length of training depending on length of absence and specialty board eligibility requirements.



**Teammates should assist colleagues in need and equitably reintegrate them upon return.**

**VI.D. Fatigue Mitigation**

**VI.D.1. Programs must:**

- VI.D.1.a)** educate all faculty members and residents to recognize the signs of fatigue and sleep deprivation; <sup>(Core)</sup>
- VI.D.1.b)** educate all faculty members and residents in alertness management and fatigue mitigation processes; and, <sup>(Core)</sup>
- VI.D.1.c)** encourage residents to use fatigue mitigation processes to manage the potential negative effects of fatigue on patient care and learning. <sup>(Detail)</sup>

**Background and Intent:** Providing medical care to patients is physically and mentally demanding. Night shifts, even for those who have had enough rest, cause fatigue. Experiencing fatigue in a supervised environment during training prepares residents for managing fatigue in practice. It is expected that programs adopt fatigue mitigation processes and ensure that there are no negative consequences and/or stigma for using fatigue mitigation strategies.

This requirement emphasizes the importance of adequate rest before and after clinical responsibilities. Strategies that may be used include, but are not limited to, strategic napping; the judicious use of caffeine; availability of other caregivers; time management to maximize sleep off-duty; learning to recognize the signs of fatigue, and self-monitoring performance and/or asking others to monitor performance; remaining active to promote alertness; maintaining a healthy diet; using relaxation techniques to fall asleep; maintaining a consistent sleep routine; exercising regularly; increasing sleep time before and after call; and ensuring sufficient sleep recovery periods.

- VI.D.2.** Each program must ensure continuity of patient care, consistent with the program's policies and procedures referenced in VI.C.2–VI.C.2.b), in the event that a resident may be unable to perform their patient care responsibilities due to excessive fatigue. <sup>(Core)</sup>
- VI.D.3.** The program, in partnership with its Sponsoring Institution, must ensure adequate sleep facilities and safe transportation options for residents who may be too fatigued to safely return home. <sup>(Core)</sup>

**VI.E. Clinical Responsibilities, Teamwork, and Transitions of Care**

**VI.E.1. Clinical Responsibilities**

**The clinical responsibilities for each resident must be based on PGY level, patient safety, resident ability, severity and complexity of patient illness/condition, and available support services. <sup>(Core)</sup>**



**Background and Intent:** The changing clinical care environment of medicine has meant that work compression due to high complexity has increased stress on residents. Faculty members and program directors need to make sure residents function in an environment that has safe patient care and a sense of resident well-being. Some Review Committees have addressed this by setting limits on patient admissions, and it is an essential responsibility of the program director to monitor resident workload. Workload should be distributed among the resident team and interdisciplinary teams to minimize work compression.

**VI.E.2. Teamwork**

Residents must care for patients in an environment that maximizes communication. This must include the opportunity to work as a member of effective interprofessional teams that are appropriate to the delivery of care in the specialty and larger health system. <sup>(Core)</sup>

**VI.E.3. Transitions of Care**

- VI.E.3.a) Programs must design clinical assignments to optimize transitions in patient care, including their safety, frequency, and structure. <sup>(Core)</sup>
- VI.E.3.b) Programs, in partnership with their Sponsoring Institutions, must ensure and monitor effective, structured hand-over processes to facilitate both continuity of care and patient safety. <sup>(Core)</sup>
- VI.E.3.c) Programs must ensure that residents are competent in communicating with team members in the hand-over process. <sup>(Outcome)</sup>
- VI.E.3.d) Programs and clinical sites must maintain and communicate schedules of attending physicians and residents currently responsible for care. <sup>(Core)</sup>
- VI.E.3.e) Each program must ensure continuity of patient care, consistent with the program's policies and procedures referenced in VI.C.2-VI.C.2.b), in the event that a resident may be unable to perform their patient care responsibilities due to excessive fatigue or illness, or family emergency. <sup>(Core)</sup>

**VI.F. Clinical Experience and Education**

*Programs, in partnership with their Sponsoring Institutions, must design an effective program structure that is configured to provide residents with educational and clinical experience opportunities, as well as reasonable opportunities for rest and personal activities.*

**Background and Intent:** In the new requirements, the terms “clinical experience and education,” “clinical and educational work,” and “clinical and educational work hours”

replace the terms “duty hours,” “duty periods,” and “duty.” These changes have been made in response to concerns that the previous use of the term “duty” in reference to number of hours worked may have led some to conclude that residents’ duty to “clock out” on time superseded their duty to their patients.

**VI.F.1. Maximum Hours of Clinical and Educational Work per Week**

Clinical and educational work hours must be limited to no more than 80 hours per week, averaged over a four-week period, inclusive of all in-house clinical and educational activities, clinical work done from home, and all moonlighting. <sup>(Core)</sup>

**Background and Intent:** Programs and residents have a shared responsibility to ensure that the 80-hour maximum weekly limit is not exceeded. While the requirement has been written with the intent of allowing residents to remain beyond their scheduled work periods to care for a patient or participate in an educational activity, these additional hours must be accounted for in the allocated 80 hours when averaged over four weeks.

***Scheduling***

While the ACGME acknowledges that, on rare occasions, a resident may work in excess of 80 hours in a given week, all programs and residents utilizing this flexibility will be required to adhere to the 80-hour maximum weekly limit when averaged over a four-week period. Programs that regularly schedule residents to work 80 hours per week and still permit residents to remain beyond their scheduled work period are likely to exceed the 80-hour maximum, which would not be in substantial compliance with the requirement. These programs should adjust schedules so that residents are scheduled to work fewer than 80 hours per week, which would allow residents to remain beyond their scheduled work period when needed without violating the 80-hour requirement. Programs may wish to consider using night float and/or making adjustments to the frequency of in-house call to ensure compliance with the 80-hour maximum weekly limit.

***Oversight***

With increased flexibility introduced into the Requirements, programs permitting this flexibility will need to account for the potential for residents to remain beyond their assigned work periods when developing schedules, to avoid exceeding the 80-hour maximum weekly limit, averaged over four weeks. The ACGME Review Committees will strictly monitor and enforce compliance with the 80-hour requirement. Where violations of the 80-hour requirement are identified, programs will be subject to citation and at risk for an adverse accreditation action.

***Work from Home***

While the requirement specifies that clinical work done from home must be counted toward the 80-hour maximum weekly limit, the expectation remains that scheduling be structured so that residents are able to complete most work on site during scheduled clinical work hours without requiring them to take work home. The new requirements acknowledge the changing landscape of medicine, including electronic health records, and the resulting increase in the amount of work residents choose to do from home. The requirement provides flexibility for residents to do this while ensuring that the time spent by residents completing clinical work from home is accomplished within the 80-hour weekly maximum. Types of work from home that must be counted include using an

electronic health record and taking calls from home. Reading done in preparation for the following day's cases, studying, and research done from home do not count toward the 80 hours. Resident decisions to leave the hospital before their clinical work has been completed and to finish that work later from home should be made in consultation with the resident's supervisor. In such circumstances, residents should be mindful of their professional responsibility to complete work in a timely manner and to maintain patient confidentiality.

During the public comment period many individuals raised questions and concerns related to this change. Some questioned whether minute by minute tracking would be required; in other words, if a resident spends three minutes on a phone call and then a few hours later spends two minutes on another call, will the resident need to report that time. Others raised concerns related to the ability of programs and institutions to verify the accuracy of the information reported by residents. The new requirements are not an attempt to micromanage this process. Residents are to track the time they spend on clinical work from home and to report that time to the program. Decisions regarding whether to report infrequent phone calls of very short duration will be left to the individual resident. Programs will need to factor in time residents are spending on clinical work at home when schedules are developed to ensure that residents are not working in excess of 80 hours per week, averaged over four weeks. There is no requirement that programs assume responsibility for documenting this time. Rather, the program's responsibility is ensuring that residents report their time from home and that schedules are structured to ensure that residents are not working in excess of 80 hours per week, averaged over four weeks.

***PGY-1 and PGY-2 Residents***

PGY-1 and PGY-2 residents may not have the experience to make decisions about when it is appropriate to utilize flexibility or may feel pressured to use it when unnecessary. Programs are responsible for ensuring that residents are provided with manageable workloads that can be accomplished during scheduled work hours. This includes ensuring that a resident's assigned direct patient load is manageable, that residents have appropriate support from their clinical teams, and that residents are not overburdened with clerical work and/or other non-physician duties.

**VI.F.2. Mandatory Time Free of Clinical Work and Education**

- VI.F.2.a)** The program must design an effective program structure that is configured to provide residents with educational opportunities, as well as reasonable opportunities for rest and personal well-being. <sup>(Core)</sup>
- VI.F.2.b)** Residents should have eight hours off between scheduled clinical work and education periods. <sup>(Detail)</sup>
- VI.F.2.b).(1)** There may be circumstances when residents choose to stay to care for their patients or return to the hospital with fewer than eight hours free of clinical experience and education. This must occur within the context of the 80-hour and the one-day-off-in-seven requirements. <sup>(Detail)</sup>

**Background and Intent:** While it is expected that resident schedules will be structured to ensure that residents are provided with a minimum of eight hours off between scheduled work periods, it is recognized that residents may choose to remain beyond their scheduled time, or return to the clinical site during this time-off period, to care for a patient. The requirement preserves the flexibility for residents to make those choices. It is also noted that the 80-hour weekly limit (averaged over four weeks) is a deterrent for scheduling fewer than eight hours off between clinical and education work periods, as it would be difficult for a program to design a schedule that provides fewer than eight hours off without violating the 80-hour rule.

**VI.F.2.c)** Residents must have at least 14 hours free of clinical work and education after 24 hours of in-house call. <sup>(Core)</sup>

**Background and Intent:** Residents have a responsibility to return to work rested, and thus are expected to use this time away from work to get adequate rest. In support of this goal, residents are encouraged to prioritize sleep over other discretionary activities.

**VI.F.2.d)** Residents must be scheduled for a minimum of one day in seven free of clinical work and required education (when averaged over four weeks). At-home call cannot be assigned on these free days. <sup>(Core)</sup>

**Background and Intent:** The requirement provides flexibility for programs to distribute days off in a manner that meets program and resident needs. It is strongly recommended that residents' preference regarding how their days off are distributed be considered as schedules are developed. It is desirable that days off be distributed throughout the month, but some residents may prefer to group their days off to have a "golden weekend," meaning a consecutive Saturday and Sunday free from work. The requirement for one free day in seven should not be interpreted as precluding a golden weekend. Where feasible, schedules may be designed to provide residents with a weekend, or two consecutive days, free of work. The applicable Review Committee will evaluate the number of consecutive days of work and determine whether they meet educational objectives. Programs are encouraged to distribute days off in a fashion that optimizes resident well-being, and educational and personal goals. It is noted that a day off is defined in the ACGME Glossary of Terms as "one (1) continuous 24-hour period free from all administrative, clinical, and educational activities."

**VI.F.3. Maximum Clinical Work and Education Period Length**

**VI.F.3.a)** Clinical and educational work periods for residents must not exceed 24 hours of continuous scheduled clinical assignments. <sup>(Core)</sup>

**Background and Intent:** The Task Force examined the question of "consecutive time on task." It examined the research supporting the current limit of 16 consecutive hours of time on task for PGY-1 residents; the range of often conflicting impacts of this requirement on patient safety, clinical care, and continuity of care by resident teams; and resident learning found in the literature. Finally, it heard a uniform request by the specialty societies, certifying boards, membership societies and organizations, and senior residents to repeal this requirement. It heard conflicting perspectives from

resident unions, a medical student association, and a number of public advocacy groups, some arguing for continuation of the requirement, others arguing for extension of the requirement to all residents.

Of greatest concern to the Task Force were the observations of disruption of team care and patient care continuity brought about with residents beyond the PGY-1 level adhering to differing requirements. The graduate medical education community uniformly requested that the Task Force remove this requirement. The most frequently-cited reason for this request was the complete disruption of the team, separating the PGY-1 from supervisory faculty members and residents who were best able to judge the ability of the resident and customize the supervision of patient care for each PGY-1. Cited nearly as frequently was the separation of the PGY-1 from the team, delaying maturation of clinical skills, and threatening to create a “shift” mentality in disciplines where overnight availability to patients is essential in delivery of care.

The Task Force examined the impact of the request to consider 16-consecutive-hour limits for all residents, and rejected the proposition. It found that model incompatible with the actual practice of medicine and surgery in many specialties, excessively limiting in configuration of clinical services in many disciplines, and potentially disruptive of the inculcation of responsibility and professional commitment to altruism and placing the needs of patients above those of the physician.

After careful consideration of the information available, the testimony and position of all parties submitting information, and presentations to the Task Force, the Task Force removed the 16-hour-consecutive-time-on-task requirement for PGY-1 residents. It remains crucial that programs ensure that PGY-1 residents are supervised in compliance with the applicable Program Requirements, and that resident well-being is prioritized as described in Section VI.C. of these requirements.

**VI.F.3.a).(1)**

Up to four hours of additional time may be used for activities related to patient safety, such as providing effective transitions of care, and/or resident education.  
(Core)

**VI.F.3.a).(1).(a)**

Additional patient care responsibilities must not be assigned to a resident during this time. (Core)

**Background and Intent:** The additional time referenced in VI.F.3.a).(1) should not be used for the care of new patients. It is essential that the resident continue to function as a member of the team in an environment where other members of the team can assess resident fatigue, and that supervision for post-call residents is provided. This 24 hours and up to an additional four hours must occur within the context of 80-hour weekly limit, averaged over four weeks.

**VI.F.4.**

**Clinical and Educational Work Hour Exceptions**

**VI.F.4.a)**

In rare circumstances, after handing off all other responsibilities, a resident, on their own initiative, may elect to remain or return to the clinical site in the following circumstances:

- VI.F.4.a).(1)** to continue to provide care to a single severely ill or unstable patient; <sup>(Detail)</sup>
- VI.F.4.a).(2)** humanistic attention to the needs of a patient or family; or, <sup>(Detail)</sup>
- VI.F.4.a).(3)** to attend unique educational events. <sup>(Detail)</sup>
- VI.F.4.b)** These additional hours of care or education will be counted toward the 80-hour weekly limit. <sup>(Detail)</sup>

**Background and Intent:** This requirement is intended to provide residents with some control over their schedules by providing the flexibility to voluntarily remain beyond the scheduled responsibilities under the circumstances described above. It is important to note that a resident may remain to attend a conference, or return for a conference later in the day, only if the decision is made voluntarily. Residents must not be required to stay. Programs allowing residents to remain or return beyond the scheduled work and clinical education period must ensure that the decision to remain is initiated by the resident and that residents are not coerced. This additional time must be counted toward the 80-hour maximum weekly limit.

- VI.F.4.c)** A Review Committee may grant rotation-specific exceptions for up to 10 percent or a maximum of 88 clinical and educational work hours to individual programs based on a sound educational rationale.

However, the Review Committee for Obstetrics and Gynecology does not allow requests for exceptions to the 80-hour per week limitation on resident duty hours.

**VI.F.5. Moonlighting**

- VI.F.5.a)** Moonlighting must not interfere with the ability of the resident to achieve the goals and objectives of the educational program, and must not interfere with the resident's fitness for work nor compromise patient safety. <sup>(Core)</sup>
- VI.F.5.b)** Time spent by residents in internal and external moonlighting (as defined in the ACGME Glossary of Terms) must be counted toward the 80-hour maximum weekly limit. <sup>(Core)</sup>
- VI.F.5.c)** PGY-1 residents are not permitted to moonlight. <sup>(Core)</sup>

**Background and Intent:** For additional clarification of the expectations related to moonlighting, please refer to the Common Program Requirement FAQs (available at <http://www.acgme.org/What-We-Do/Accreditation/Common-Program-Requirements>).

**VI.F.6. In-House Night Float**



Night float must occur within the context of the 80-hour and one-day-off-in-seven requirements. <sup>(Core)</sup>

**Background and Intent:** The requirement for no more than six consecutive nights of night float was removed to provide programs with increased flexibility in scheduling.

**VI.F.7. Maximum In-House On-Call Frequency**

Residents must be scheduled for in-house call no more frequently than every third night (when averaged over a four-week period). <sup>(Core)</sup>

**VI.F.8. At-Home Call**

**VI.F.8.a)** Time spent on patient care activities by residents on at-home call must count toward the 80-hour maximum weekly limit. The frequency of at-home call is not subject to the every-third-night limitation, but must satisfy the requirement for one day in seven free of clinical work and education, when averaged over four weeks. <sup>(Core)</sup>

**VI.F.8.a).(1)** At-home call must not be so frequent or taxing as to preclude rest or reasonable personal time for each resident. <sup>(Core)</sup>

**VI.F.8.b)** Residents are permitted to return to the hospital while on at-home call to provide direct care for new or established patients. These hours of inpatient patient care must be included in the 80-hour maximum weekly limit. <sup>(Detail)</sup>

**Background and Intent:** This requirement has been modified to specify that clinical work done from home when a resident is taking at-home call must count toward the 80-hour maximum weekly limit. This change acknowledges the often significant amount of time residents devote to clinical activities when taking at-home call, and ensures that taking at-home call does not result in residents routinely working more than 80 hours per week. At-home call activities that must be counted include responding to phone calls and other forms of communication, as well as documentation, such as entering notes in an electronic health record. Activities such as reading about the next day's case, studying, or research activities do not count toward the 80-hour weekly limit.

In their evaluation of residency/fellowship programs, Review Committees will look at the overall impact of at-home call on resident/fellow rest and personal time.

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**\*Core Requirements:** Statements that define structure, resource, or process elements essential to every graduate medical educational program.

**†Detail Requirements:** Statements that describe a specific structure, resource, or process, for achieving compliance with a Core Requirement. Programs and sponsoring institutions in substantial compliance with the Outcome Requirements may utilize alternative or innovative approaches to meet Core Requirements.



**\*Outcome Requirements:** Statements that specify expected measurable or observable attributes (knowledge, abilities, skills, or attitudes) of residents or fellows at key stages of their graduate medical education.

**Osteopathic Recognition**

For programs with or applying for Osteopathic Recognition, the Osteopathic Recognition Requirements also apply ([www.acgme.org/OsteopathicRecognition](http://www.acgme.org/OsteopathicRecognition)).

**Exhibit 6**



## **Guidelines for the Chronic Use of Opioid Analgesics**

*Adopted as policy by the Federation of State Medical Boards  
April 2017*

### **INTRODUCTION**

In April 2015, the Federation of State Medical Boards (FSMB) Chair, J. Daniel Gifford, MD, FACP, appointed the Workgroup on FSMB's *Model Policy for the Use of Opioid Analgesics in the Treatment of Chronic Pain* to review the current science for treating chronic pain with opioid analgesics and to revise the Model Policy as appropriate.

To accomplish this charge, the workgroup conducted a thorough review and analysis of FSMB's existing policy document and other state and federal policies on the prescribing of opioids in the treatment of pain, including the March 2016 *CDC Guideline for Prescribing Opioids for Chronic Pain* (<https://www.cdc.gov/drugoverdose/prescribing/guideline.html>)

In updating its existing policy, the FSMB sought input from a diverse group of medical and policy stakeholders that ranged from experts in pain medicine and addiction to government officials and other thought leaders. Over the course of the last 12 months, the workgroup met on several occasions to examine and explore the key elements required to ensure FSMB's policy document remains relevant and is sufficiently comprehensive to serve as a prescribing guideline and resource for state medical and osteopathic boards and clinicians.

This policy document includes relevant recommendations identified by the workgroup, and is in keeping with recent releases of advisories issued by the CDC and FDA. This policy is intended as a resource providing overall guidance to state medical and osteopathic boards in assessing physicians' management of pain in their patients and whether opioid analgesics are used in a medically appropriate manner.

### **FSMB GUIDELINES FOR THE CHRONIC USE OF OPIOID ANALGESICS**

#### **Section 1 – PREAMBLE**

The diagnosis and treatment of pain is integral to the practice of medicine<sup>2,18-21</sup>. In order to implement best practices for responsible opioid prescribing, clinicians must understand the relevant pharmacologic and clinical issues in the use of opioid analgesics and should obtain sufficient targeted continuing education and training on the safe prescribing of opioids and other analgesics as well as training in multimodal treatments.

## Section 2 – FOCUS OF GUIDELINES

The focus of the Guidelines that follow is on the general overall safe and evidence-based prescribing of opioids and treatment of chronic, non-cancer pain with the specific **limitation and restriction** that these Guidelines do not operate to create any specific standard of care, which standard must depend upon fact-specific totality of circumstances surrounding specific quality-of-care events. The Guidelines recognize that there is not just one appropriate strategy to accomplish the goals of these Guidelines. Effective means of achieving the goals of these Guidelines vary widely depending on the type and causes of the patient's pain, the preferences of the clinician and the patient, the resources available at the time of care, and other concurrent issues beyond the scope of these Guidelines.

These Guidelines that follow do not encourage the prescribing of opioids over other pharmacological and nonpharmacological means of treatment but rather the Guidelines recognize the responsibility of clinicians to view pain management as essential to quality of medical practice and to the quality of life for patients who suffer from pain.

Finally, the Guidelines that follow are not intended for the treatment of acute pain, acute pain management in the perioperative setting, emergency care, cancer-related pain, palliative care, or end-of-life care. These Guidelines may apply most directly to the treatment of chronic pain lasting more than three months in duration or past the time of normal tissue healing, however many of the strategies mentioned here are also relevant to responsible prescribing and the mitigation of risks associated with other controlled substances in the treatment of pain.

## Section 3 – DEFINITIONS

For the purposes of this Model Policy, the following terms are defined as shown.

**Aberrant Behaviors:** Certain behaviors may constitute aberrant behaviors. For example, obtaining prescriptions for the same or similar drugs from more than one clinician or other health care provider without the treating clinician's knowledge is aberrant behavior, as is use of illicit drugs.

**Abuse:** Abuse has been described as a pattern of drug use that exists despite adverse consequences or risk of consequences. Abuse of a prescription medication involves its use in a manner that deviates from accepted medical, legal, and social standards, generally to achieve a euphoric state ("high") or that is other than the purpose for which the medication was prescribed<sup>14</sup>. Please also see "Substance Use Disorder".

**Addiction:** A common definition of addiction is that it is "a primary, chronic, neurobiologic disease, whose development and manifestations are influenced by genetic, psychosocial, and environmental factors"<sup>14</sup>. Addiction often is said to be characterized by behaviors that include impaired control over drug use, craving, compulsive use, and continued use despite harm<sup>14</sup>. A newer definition, adopted by the American Society of Addiction Medicine in 2011, describes addiction as "a primary, chronic disease of brain reward, motivation, memory and related

circuitry. Dysfunction in these circuits leads to characteristic biological, psychological, social and spiritual manifestations. This is reflected in an individual pathologically pursuing reward and/or relief by substance use and other behaviors. Addiction is characterized by inability to consistently abstain, impairment in behavioral control, craving, diminished recognition of significant problems with one's behaviors and interpersonal relationships, and a dysfunctional emotional response. Like other chronic diseases, addiction often involves cycles of relapse and remission. Without treatment or engagement in recovery activities, addiction is progressive and can result in disability or premature death"<sup>24</sup>. (As discussed below, physical dependence and tolerance are expected physiological consequences of extended opioid therapy for pain and in this context do not indicate the presence of addiction.) Please also see "Substance Use Disorder".

**Controlled Substance:** A controlled substance is a drug that is subject to special requirements under the federal Controlled Substances Act of 1970 (CSA)<sup>13</sup>, which is designed to ensure both the availability and control of regulated substances. Under the CSA, availability of regulated drugs for medical purposes is accomplished through a system that establishes quotas for drug production and a distribution system that closely monitors the importation, manufacture, distribution, prescribing, dispensing, administering, and possession of controlled drugs. Civil and criminal sanctions for serious violations of the statute are part of the government's control apparatus. The Code of Federal Regulations (Title 21, Chapter 2) implements the CSA. The CSA provides that responsibility for scheduling controlled substances is shared between the Food and Drug Administration (FDA) and the DEA. In granting regulatory authority to these agencies, the Congress noted that both public health and public safety needs are important and that neither takes primacy over the other. To accomplish this, the Congress provided guidance in the form of factors that must be considered by the FDA and DEA when assessing public health and safety issues related to a new drug or one that is being considered for rescheduling or removal from control.

The CSA does not limit the amount of drug prescribed, the duration for which it is prescribed, or the period for which a prescription is valid (although some states do impose such limits).

Most potent opioid analgesics are classified in Schedules II under the CSA, indicating that they have a significant potential for abuse and a currently accepted medical use in treatment in the U.S. (with certain restrictions), and that abuse of the drug may lead to severe psychological or physical dependence. Although the scheduling system provides a rough guide to abuse potential, all controlled medications have some potential for abuse.

**Dependence:** Physical dependence is a state of biologic adaptation that is evidenced by a withdrawal syndrome when the drug is abruptly discontinued or the dose rapidly reduced, and/or by the administration of an antagonist<sup>14</sup>. It is important to distinguish addiction from the type of physical dependence that can and does occur within the context of good medical care, as when a patient on long-term opioid analgesics for pain becomes physically dependent on the analgesic. This distinction is reflected in the two primary diagnostic classification systems used by health care professionals: the *International Classification of Mental and Behavioral Disorders, 10th Edition* (ICD-10) of the World Health Organization<sup>50</sup>, and the *Diagnostic and Statistical Manual (DSM)* of the American Psychiatric Association<sup>51</sup>. In the DSM-IV-TR, a

diagnosis of “substance dependence” meant addiction. In the DSM-5, the term *dependence* is reestablished in its original meaning of physiological dependence. When symptoms are sufficient to meet criteria for substance misuse or addiction, the term “substance use disorder” is used, accompanied by severity ratings<sup>49</sup>.

It may be important to clarify this distinction during the informed consent process, so that the patient (and family) understands that physical dependence and tolerance are likely to occur if opioids are taken regularly over a period of time, but that the risk of addiction is relatively low, although estimates do vary. Discontinuing chronic opioid therapy may be difficult, even in the absence of addiction. According to the World Health Organization, “The development of tolerance and physical dependence denote normal physiologic adaptations of the body to the presence of an opioid”<sup>50</sup>. Consequently, physical dependence alone is neither necessary nor sufficient to diagnose addiction<sup>51,52</sup>. Please also see “Substance Use Disorder”.

**Diversion:** Drug diversion is defined as the intentional transfer of a controlled substance from authorized to unauthorized possession or channels of distribution<sup>53-54</sup>. The federal Controlled Substances Act (21 U.S.C. §§ 801 et seq.) establishes a closed system of distribution for drugs that are classified as controlled substances. Records must be kept from the time a drug is manufactured to the time it is dispensed. Health care professionals who are authorized to prescribe, dispense, and otherwise control access to such drugs are required to register with the DEA<sup>13,55</sup>.

Pharmaceuticals that make their way outside this closed distribution system are said to have been “diverted”<sup>55</sup>, and the individuals responsible for the diversion (including patients) are in violation of federal law, and often corresponding state laws as well.

Experience shows that the degree to which a prescribed medication is misused depends in large part on how easily it is redirected (diverted) from the legitimate distribution system<sup>7,8,54</sup>.

**Misuse:** The term misuse (also called nonmedical use) encompasses all uses of a prescription medication other than those that are directed by a clinician and used by a patient within the law and the requirements of good medical practice<sup>14</sup>. Please also see “Substance Use Disorder”.

**Opioid:** An opioid is an opium-like compound that binds to one or more of the three opioid receptors of the body. The class includes naturally occurring and synthetic or semi-synthetic opioid drugs or medications, as well as endogenous opioid peptides<sup>19</sup>. Most clinicians use the terms “opiate” and “opioid” interchangeably, but toxicologists (who perform and interpret drug tests) make a clear distinction between them. “Opioid” is the broader term because it includes the entire class of agents that act at opioid receptors in the CNS, whereas “opiates” refers to natural compounds derived from the opium plant but not semisynthetic opioid derivatives of opiates or completely synthetic agents. Thus, drug tests that are “positive for opiates” have detected one of these compounds or a metabolite of heroin, 6-monoacetyl morphine (MAM). Drug tests that are “negative for opiates” have found no detectable levels of opiates in the sample, even though other opioids that were not tested for—including the most common currently used and misused prescription opioids—may be present in the sample that was analyzed<sup>34,40-41</sup>.

**Pain:** An unpleasant and potentially disabling sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage. *Acute pain* is the normal, predictable physiological response to a noxious chemical, thermal or mechanical stimulus and typically is associated with invasive procedures, trauma and disease. Acute pain generally is time limited, lasting six weeks or less<sup>2</sup>. *Chronic pain* is a state in which pain persists beyond the usual course of an acute disease or healing of an injury (e.g., more than three months). It may or may not be associated with an acute or chronic pathologic process that causes continuous or intermittent pain over a period of months or years. *Chronic non-cancer related pain* is chronic pain that is not associated with cancer and does not occur at the end of life<sup>2,56</sup>. *Opioid-induced hyperalgesia* may develop as a result of long-term opioid use in the treatment of pain. *Primary hyperalgesia* is pain sensitivity that occurs directly in the damaged tissues, while *secondary hyperalgesia* occurs in surrounding undamaged tissues. Human and animal studies have demonstrated that primary or secondary hyperalgesia can develop in response to both chronic and acute exposure to opioids. Hyperalgesia can be severe enough to warrant discontinuation of opioid treatment<sup>57</sup>.

**Prescription Drug Monitoring Program:** As a patient safety tool, almost all states have enacted laws that establish prescription drug monitoring programs (PDMPs) to facilitate the collection, analysis, and reporting of information on the prescribing and dispensing of controlled substances. Most such programs employ electronic data transfer systems, under which prescription information is transmitted from the dispensing pharmacy to a state agency, which collates and analyzes the information<sup>1,12</sup>. After analyzing the efficacy of PDMPs, the Government Accountability Office (GAO) concluded that such programs have the potential to help law enforcement and regulatory agencies rapidly identify and investigate activities that may involve illegal prescribing, dispensing or consumption of controlled substances. Where real-time data are available, PDMPs also can help to prevent prescription drug misuse, overdose, and diversion by allowing clinicians to determine whether a patient is receiving prescriptions for controlled substances from other clinicians, as well as whether the patient has filled or refilled an order for an opioid the clinician has prescribed<sup>12,58-59</sup>.

**Substance Use Disorder:** In the DSM-5, Substance Use Disorder encompasses what was previously classified as abuse, dependence, misuse, and tolerance. Under the DSM-5 definition of Substance Use Disorder a patient needs to meet any 2 of 11 criteria in the same 12 months. The severity is based on the number of criteria (i.e., mild is 2-3 criteria, moderate is 4-5 criteria, and severe is 6 or more criteria). Criteria are grouped into impaired control (i.e., taken in larger amounts or over longer time than was intended; persistent desire or unsuccessful efforts to cut down or control use; great deal of time spent in activities to obtain, use or recover from its effects; craving or strong desire to use); social impairment (i.e., use resulting in a failure to fulfill major role obligations at work, school, or home; continued use despite persistent or recurrent social or interpersonal problems caused by the use; important social, occupational, or recreational activities are given up or reduced due to use); risky use (i.e., recurrent use in situations in which it is physically dangerous; use despite knowledge of having a persistent physical or psychological problem that is caused or exacerbated by use); and pharmacological properties (i.e., tolerance; withdrawal).



**Tolerance:** Tolerance is a state of physiologic adaptation in which exposure to a drug induces changes that result in diminution of one or more of the drug's effects over time. Tolerance is common in opioid treatment and is not the same as addiction<sup>14</sup>. Please also see "Substance Use Disorder".

### **Section 3 - FSMB GUIDELINES**

State medical boards may adopt the following criteria for use in evaluating a clinician's management of a patient with pain, including the clinician's prescribing of opioid analgesics. Such adoption is subject to the **Guidelines, Limitations and Restrictions** previously set forth.

#### **Patient Evaluation and Risk Stratification**

The medical record should document the presence of one or more recognized medical indications and absence of psychosocial contraindications for prescribing an opioid analgesic<sup>3</sup> and reflect an appropriately detailed patient evaluation<sup>22</sup>. An evaluation should be completed and documented concurrent with the decision of whether to prescribe an opioid analgesic.

The nature and extent of the evaluation depends on the type of pain and the context in which it occurs. Assessment of the patient's pain should include the nature and intensity of the pain, past and current treatments for the pain, any underlying or co-occurring disorders and conditions, and the effect of the pain on the patient's physical and psychological functioning<sup>17</sup>.

For every patient, the initial assessment and evaluation should include a systems review and relevant physical examination, as well as objective markers of disease or diagnostic markers as indicated. Also, functional assessment, including social and vocational assessment, is useful in identifying supports and obstacles to treatment and rehabilitation.

Assessment of the patient's personal and family history of alcohol or drug abuse and relative risk for substance use disorder also should be part of the initial evaluation<sup>5,6,9-11,27</sup>, and ideally should be completed prior to a decision as to whether to prescribe opioid analgesics<sup>37-39</sup>. This can be done through a careful clinical interview, which should also inquire into any history of physical, emotional or sexual abuse, because those are risk factors for substance use disorder<sup>17</sup>. Use of validated screening tools for substance use disorder may be used for collecting and evaluating information and determining the patient's level of risk.

Patients who have a history of substance use disorder as defined by DSM-5 are at an elevated risk for failure of opioid analgesic therapy to achieve the goals of improved comfort and function, and also are at high risk for relapse. Treatment of a patient who has a history of substance use disorder may involve consultation with an addiction specialist before opioid therapy is initiated (and follow-up, as needed). Additionally, patients who have a substance use disorder as defined by the DSM-5, require additional support if opioid therapy is necessitated and should not receive opioid therapy until they are established in a treatment/recovery program<sup>17</sup> or alternatives are established, such as co-management with an addiction professional. Clinicians who treat patients with chronic pain are encouraged to also be knowledgeable about the identification and treatment of substance use disorder, including the

role of replacement agonists such as methadone and buprenorphine. Some non-addiction specialist clinicians may choose to directly treat patients with substance use disorder. This may include becoming eligible to treat substance use disorder using office-based buprenorphine as part of medication-assisted treatment.

Assessment of the patient's personal and family history of mental health disorders should be part of the initial evaluation, and ideally should be completed prior to a decision as to whether to prescribe opioid analgesics. All patients should be screened for depression and other mental health disorders, as part of risk evaluation. Patients with untreated depression and other mental health disorders are at increased risk for misuse or abuse of controlled medications, including addiction and overdose. Additionally, untreated depression can interfere with the resolution of pain.

The patient evaluation may include information from family members and/or significant others<sup>10-11,31-32</sup>. It is strongly recommended that the state prescription drug monitoring program (PDMP) be consulted prior to initiating opioid therapy and at appropriate intervals thereafter to determine whether the patient is receiving prescriptions from any other clinicians, and the results obtained from the PDMP should be reviewed.

In working with a patient who is taking opioids prescribed by another clinician—particularly a patient on high doses—the evaluation and risk stratification assume even greater importance<sup>9-11</sup>. Therefore, to ensure a smooth transition of care, clinicians are encouraged to collaborate with the primary prescriber.

Caution should be used with the administration of chronic opioids in women of childbearing age, as chronic opioid therapy during pregnancy increases risk of harm to the newborn. Opioids should be administered with caution in breastfeeding women, as some opioids may be transferred to the baby in breast milk. When chronic opioid therapy is used for an elderly patient, clinicians should carefully consider the initial dose, titrating slowly upwards if necessary, using a longer dosing interval, and monitoring more frequently. Patients at risk for sleep disordered breathing are at increased risk for harm with the use of chronic opioid therapy. Clinicians should consider the use of a screening tool for obstructive sleep apnea and refer patients for proper evaluation and treatment when indicated.

The patient evaluation should include most of the following elements:

- Medical history and physical examination targeted to the pain condition
- Nature and intensity of the pain
- Current and past treatments, including interventional treatments, with response to each treatment
- Underlying or co-existing diseases or conditions, including those which could complicate treatment (i.e. obesity, renal disease, sleep apnea, COPD, etc.)
- Effect of pain on physical and psychological functioning
- Personal and family history of substance use disorder
- History of psychiatric disorders (bipolar, ADD/ADHD, sociopathic, borderline, major depressive disorder)

- Post-traumatic stress disorder (PTSD)
- Medical indication(s) for use of opioids
- Review of the PDMP results
- Obtain consultation with other clinicians when applicable
- Urine, blood or other types of biological samples and diagnostic markers

#### **Development of a Treatment Plan and Goals**

The goals of pain treatment include reasonably attainable improvement in pain to decrease suffering and to increase function; improvement in pain-associated symptoms such as sleep disturbance, depression, and anxiety; screening for side effects of treatment; and avoidance of unnecessary or excessive use of medications<sup>2,4</sup>. There should be a balance between monitoring for efficacy and side effects with the use of medications for the shortest duration appropriate.

The treatment plan and goals should be established as early as possible in the treatment process and revisited regularly, so as to provide clear-cut, individualized objectives to guide the choice of therapies<sup>22</sup> for both the clinician and the patient.

The treatment plan may contain information supporting the selection of therapies, both pharmacologic (medications other than opioids to include anti-inflammatories, acetaminophen, and selected antidepressants and anticonvulsants) interventional, and non-pharmacologic therapies such as cognitive behavioral therapy, massage, exercise, multimodal pain treatment, and osteopathic manipulative treatment. The plan should document any further diagnostic evaluations, consultations or referrals, or additional therapies that have been considered to the extent they are available.

#### **Informed Consent and Treatment Agreement**

The decision to initiate chronic opioid therapy is a shared decision between the clinician and the patient. The clinician should discuss the risks and benefits of the treatment plan (including any proposed use of opioid analgesics) with the patient. If opioids are prescribed, the patient (and possibly family members) should be counseled on the potential risks and anticipated benefits, adverse effects of opioids, including but not limited to dependence, substance use disorder, overdose and death, as well as the safe ways to store and dispose of medications.

Use of a written informed consent and treatment agreement is recommended for long-term chronic opioid therapy<sup>9-11,19,22</sup>. Treatment agreements outline the joint responsibilities of the clinician and patient, including the patient's agreement to periodic and unannounced drug testing for opioids and other medications when deemed appropriate by the clinician with potential for substance use disorder as well as discuss with the patient how and when the PDMP will be reviewed as part of the patient's care.

Informed consent may address:

- Limited evidence as to the benefit of opioids or other pharmaceutical therapies in the management of chronic pain (except for cancer)

- Potential risks and benefits of opioid therapy
- Potential side effects (both short and long term), such as cognitive impairment and constipation
- The likelihood that tolerance to and physical dependence on the medication will develop
- Risk of drug interactions and over-sedation
- Risk of impaired motor skills (affecting driving and other tasks)
- Risk of substance use disorder, overdose and death
- The clinician's prescribing policies and expectations, including the number and frequency of prescription refills, early refills and replacement of lost or stolen medications
- Reasons for which drug therapy may be changed or discontinued (including violation of the treatment agreement) or that treatment may be discontinued without agreement by the patient.
- Education of the patient that the complete elimination of pain is not to be expected.

Treatment agreements outline the joint responsibilities of the clinician and patient<sup>19-21</sup> and are indicated for opioid or other medications with potential for substance use disorder. It is strongly recommended that treatment agreements include:

- Treatment goals in terms of pain management, restoration of function and safety
- Patient's responsibility for safe medication use (not taking more than prescribed; dangers of using in combination with alcohol, cannabis, or other substances like benzodiazepines unless closely monitored by the prescriber, etc.)
- Secure storage and safe disposal
- Patient's responsibility to obtain prescribed opioids from only one clinician or practice
- Patient's responsibility of getting the prescriptions filled at only one pharmacy
- Patient's agreement to periodic drug testing
- Clinician's responsibility to be available or to have a covering clinician available to care for unforeseen problems and to prescribe scheduled refills.

Clinicians are recommended to refrain from referring patients to the emergency department to obtain prescriptions for opioids for chronic pain that is not cancer-related or as part of palliative care or end-of-life care.

#### **Initiating an Opioid Trial**

Non-opioid and non-pharmacologic treatments should be considered before initiating opioid therapy for chronic or acute pain lasting beyond the expected duration.

When a decision is made to initiate opioid therapy, it should be presented to the patient as a therapeutic trial or test for a defined period of time (usually no more than 30 days) and with specified evaluation points including improvement in pain and function.

The clinician should explain that progress will be carefully monitored for both benefit and harm in terms of the effects of opioids on the patient's level of pain, function, and quality of life, as well as to identify any adverse events or risks to safety<sup>33</sup>.

As noted by the FDA, when initiating opioid therapy for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment, it is highly recommended that the lowest dose possible be given, beginning with a short acting opioid and/or rotating to a long acting/extended release, if indicated. Prescribers may download a medication guide of all extended-release opioids for patients at <http://www.accessdata.fda.gov/scripts/cder/daf/>. A patient counseling document available in English and Spanish through the extended-release, long-acting Risk Evaluation and Mitigation Strategy (REMS) is also available for download at <http://www.er-la-opioidrems.com/lwgUI/rems/pcd.action>.

The concurrent use of benzodiazepines and opioids, recently added as a Black Box warning by the FDA, greatly increases the risk of adverse events including death. Given this increased risk, clinicians should avoid prescribing opioid pain medication and benzodiazepines concurrently whenever possible.

While there is clinical variation in response by patients to opioid therapy at any given dosage, the CDC and some states have recommended specific dosing guidelines for opioids. Clinicians need to be aware that increasing opioid dosage beyond the current recommended guidelines may result in increased risk for substance use disorder and/or diversion. A clinician should clearly state in the medical records the rationale for using higher dosages than the current recommended guidelines, recognizing that genetic variations can significantly alter drug response, and monitor those patients prescribed such a dose with increased vigilance to assure the risks of diversion and/or overdose are minimized. The clinician should also be aware that maximum benefit to the patient may have already been obtained and increasing the dosage may not result in further therapeutic benefit, and can result in harm to the patient. Referral to, or consultation with a pain specialist for patients on higher than recommended dosages, may be considered, and dosages should not be escalated without re-evaluation of the benefits and risks.

Before prescribing methadone for its analgesic effect, it is strongly recommended that clinicians have specific training and/or experience as individual responses to methadone vary widely increasing the risk of overdose. There is a complex relationship between dose, half-life, duration of analgesic effect, and duration of respiratory depression. Specifically, the duration of analgesic effect is generally shorter than the duration of respiratory depression. The long half-life of methadone and the longer duration of respiratory depression relative to analgesia places patients at risk for overdose when titrating methadone dose for pain management.

Clinicians should consider co-prescribing naloxone for home use for all patients with opioid prescriptions in case of accidental or intentional overdose by the patient or household contacts. Patients at greatest risk of overdose include patients with a history of substance use disorder, history of prior overdose, clinical depression, patients who are taking opioids with other central nervous system depressants, or when evidence of increased risk by other measures exists (behaviors, family history, PDMP, risk assessment results).

### **Ongoing Monitoring and Adapting the Treatment Plan**

The clinician should regularly review the patient's progress, including any new information about the etiology of the pain or the patient's overall health and level of function<sup>19,31-32</sup>. When possible, collateral information about the patient's response to opioid therapy may be obtained from family members or other close contacts, as well as review of the state PDMP. The patient may be seen more frequently while the treatment plan is being initiated and the opioid dose adjusted<sup>26-33</sup>. As the patient is stabilized in the treatment regimen, follow-up visits may be scheduled as indicated by stability and risk level. Monitoring plans for a given patient should take into account the generally increased risk for dependence developing a substance use disorder and misuse the longer the patient uses them.

Continuation, modification or termination of opioid therapy for pain is contingent on the clinician's evaluation of (1) evidence of the patient's progress toward treatment objectives and (2) the absence of substantial risks or adverse events, such as signs of substance use disorder and/or diversion<sup>9-11,27</sup>. A satisfactory response to treatment would be indicated by a reduced level of pain, increased level of function, and/or improved quality of life<sup>15</sup>. Information from family members or other caregivers may be considered in evaluating the patient's response to treatment<sup>6,19-20</sup>. Use of measurement tools to assess the patient's level of pain, function, and quality of life may be helpful in documenting therapeutic outcomes<sup>6,31</sup>.

### **Periodic and Unannounced Drug Testing**

Periodic and unannounced drug testing (including chromatography) are useful in monitoring adherence to the treatment plan, as well as in detecting the use of non-prescribed drugs<sup>34-35</sup>. Drug testing is an important monitoring tool because self-reporting of medication use is not always reliable and behavioral observations may detect some problems but not others<sup>36-40</sup>. It is strongly recommended that patients being treated for addiction be tested as frequently as necessary to ensure therapeutic adherence, but for patients being treated for pain, clinical judgment trumps recommendations for frequency of testing.

Urine may be the preferred biologic specimen for testing because of its ease of collection and storage and the cost-effectiveness of such testing<sup>34</sup>. When such testing is conducted as part of pain treatment, forensic standards are generally not necessary and not in place. Collection is preferably observed especially in pain clinics; however, chain-of-custody protocols are not followed. To help ensure a valid specimen, the urine should be warm and urine specific gravity and creatinine should be measured. Initial testing may be done using class-specific immunoassay drug panels (point-of-care or laboratory-based), which typically do not identify particular drugs within a class unless the immunoassay is specific for that drug. If necessary, this can be followed up with a more specific technique, such as gas chromatography/mass spectrometry (GC/MS) or other chromatographic tests to confirm the presence or absence of a specific drug or its metabolites<sup>34</sup>. In drug testing in a pain practice, it is important to identify the specific drug and metabolites, not just the class of the drug.



Clinicians need to be aware of the limitations of available tests (such as their limited sensitivity for many opioids) and take care to order tests appropriately<sup>35</sup>. For example, when a drug test is ordered, it is important to specify that it include the opioid being prescribed<sup>34</sup>. Because of the complexities involved in interpreting drug test results, it is advisable to confirm significant or unexpected results with the laboratory toxicologist or a clinical pathologist<sup>40-41</sup>.

While immunoassay, point of care (POC) testing has its utility in the making of temporary and “on the spot” changes in clinical management, its limitations with regard to accuracy have recently been the subject of study. These limitations are such that point of care testing may not be appropriate for making definitive changes in medication management in populations at high risk for adverse outcomes until the results of confirmatory testing with more accurate methods such as liquid chromatography tandem mass spectrometry (LC-MS/MS) are obtained. A recent study on LC-MS/MS results following immunoassay POC testing in substance use disorder treatment settings found very high rates of “false negatives and positives”<sup>34,60</sup>.

Test results that suggest opioid misuse should be discussed with the patient. It is helpful to approach such a discussion in a positive, supportive fashion, so as to strengthen the physician-patient relationship and encourage healthy behaviors (as well as behavioral change where that is needed). It is recommended that both the test results and subsequent discussion with the patient be documented in the medical record<sup>34</sup>.

### **Adapting Treatment**

As noted earlier, clinicians are encouraged to consult the state’s PDMP before initiating opioids for pain and during ongoing therapy. A PDMP is important in monitoring compliance with the treatment agreement as well as identifying individuals obtaining controlled substances from multiple prescribers, and patients who may be at increased risk for overdose<sup>9-11,36,42</sup>.

If the patient’s progress is unsatisfactory, the clinician must decide whether to revise or augment the treatment plan, whether other treatment modalities should be added to or substituted for the opioid therapy, or whether a different approach—possibly involving referral to a pain specialist or other health professional—should be employed<sup>19-21,42-43</sup>.

Evidence of misuse of prescribed opioids demands prompt evaluation by the clinician, including assessment for opioid use disorder or referral to a substance use disorder treatment specialist for such assessment, and arranging for evidence-based treatment of opioid use disorder if present. Patient behaviors that require such intervention typically involve recurrent early requests for refills, multiple reports of lost or stolen prescriptions, obtaining controlled medications from multiple sources without the clinician’s knowledge, intoxication or impairment (either observed or reported), and pressuring or threatening behaviors<sup>11</sup>.

When a drug test shows the presence of illicit drugs or drugs not prescribed by a clinician, this requires action on the part of the clinician. Some aberrant behaviors are more closely associated with substance use disorder. Of greatest concern is a pattern of behavior that suggests substance use disorder, such as unsanctioned dose escalations, deteriorating function, and failure to comply with the treatment plan<sup>44</sup>.



Documented drug diversion or prescription forgery, and abusive or assaultive behaviors require a firm, immediate response<sup>10-11,22,28</sup>, which may include properly discharging a patient from the clinician's practice. Indeed, failure to respond can place the patient and others at significant risk of adverse consequences, including accidental overdose, suicide attempts, arrests and incarceration, or even death<sup>11,45-47</sup>.

### **Consultation and Referral**

It is important to consider referral to an interdisciplinary pain management program which includes modalities such as interventional pain management, physical and occupational therapy, acupuncture, or other non-pharmacologic therapies to avoid unnecessary reliance on opioids as the sole therapy for chronic or complex pain issues.

Specialty consultation should be considered if diagnosis and/or treatment for the condition manifesting as pain is outside the scope of the clinician's comfort with dosing requirements. Opioid dose level, in and of itself, does not indicate a referral. However, there is some risk associated with higher doses, and therefore, that may be an indication for consultation, depending on the clinician's training, resources and comfort level. The treating clinician, if possible, should seek a consultation with, or refer the patient to a pain, psychiatric, addiction or mental health specialist as needed.

Clinicians should be aware of treatment options for opioid use disorder and addiction (including those available in licensed opioid treatment programs [OTPs]) and those offered by an appropriately credentialed and experienced clinician through office-based opioid treatment [OBOT]), so as to make appropriate referrals when needed<sup>11,17,21,23</sup>.

### **Discontinuing Opioid Therapy**

Throughout the course of opioid therapy, the clinician and patient should regularly weigh the potential benefits and risks of continued treatment and determine whether such treatment remains appropriate<sup>28</sup>.

If opioid therapy is continued, the treatment plan may need to be adjusted to reflect the patient's changing physical status and needs, as well as to support safe and appropriate medication use<sup>10-11</sup>.

Discontinuing or tapering of opioid therapy may be required for many reasons, and ideally, clinicians will have an end strategy for patients receiving opioids at the outset of treatment. Reasons for discontinuing opioid therapy include resolution of the underlying painful condition, emergence of intolerable side effects, inadequate analgesic effect, failure to improve the patient's quality of life despite reasonable titration, failure to achieve expected pain relief or functional improvement, failure to comply with the treatment agreement, or significant aberrant medication use, including signs of addiction. Additionally, clinicians should not continue opioid treatment unless the patient has received a benefit, including demonstrated functional improvement.

If opioid therapy is discontinued, the patient who has become physically dependent should be provided a safely structured tapering regimen. Withdrawal can be managed either by the prescribing clinician or by referring the patient to an addiction specialist<sup>43</sup>. The termination of opioid therapy should not mark the end of treatment, which should continue with other modalities, either through direct care or referral to other health care specialists, as appropriate<sup>9-11</sup>.

Discontinuing opioids is not an easy process for some patients; therefore, a referral may be needed as clinicians have an obligation to provide transition therapy in order to minimize adverse outcomes.

### **Medical Records**

Every clinician who treats patients for chronic pain must maintain accurate and complete medical records. Information that should appear in the medical record includes the following:<sup>10, 11, 22, 25-26</sup>

- Copies of the signed informed consent and treatment agreement.
- The patient's medical history.
- Results of the physical examination and all laboratory tests.
- Results of the risk assessment, including results of any screening instruments used.
- A description of the treatments provided, including all medications prescribed or administered (including the date, type, dose and quantity).
- Instructions to the patient, including discussions of risks and benefits with the patient and any significant others.
- Results of ongoing monitoring of patient progress (or lack of progress) in terms of pain management and functional improvement.
- Notes on evaluations by and consultations with specialists.
- Results of queries to the state PDMP.
- Any other information used to support the initiation, continuation, revision, or termination of treatment and the steps taken in response to any aberrant medication use behaviors<sup>9-11, 16, 22, 27, 48</sup>. These may include actual copies of, or references to, medical records of past hospitalizations or treatments by other providers.
- Authorization for release of information to other treatment providers.

The medical record must include all prescription orders for opioid analgesics and other controlled substances, whether written or telephoned. In addition, written instructions for the use of all medications should be given to the patient and documented in the record<sup>13</sup>. The name, telephone number, and address of the patient's primary pharmacy should also be recorded to facilitate contact as needed<sup>11</sup>. Records should be up-to-date and maintained in an accessible manner so as to be readily available for review<sup>13</sup>.

### **Compliance with Controlled Substance Laws and Regulations**

To prescribe, dispense or administer controlled substances, the clinician must be registered with the DEA, licensed by the state in which he or she practices, and comply with applicable federal and state regulations<sup>13</sup>.

Clinicians are referred to the *Physicians' Manual of the U.S. Drug Enforcement Administration* (and any relevant documents issued by the state medical Board) for specific rules and regulations governing the use of controlled substances. Additional resources are available on the DEA's website (at [www.deadiversion.usdoj.gov](http://www.deadiversion.usdoj.gov)), as well as from (any relevant documents issued by the state medical board).

### **Section 4 – CONCLUSION**

The goal of this Model Policy is to provide state medical and osteopathic boards with an updated guideline for assessing a clinician's management of pain, so as to determine whether opioid analgesics are used in a manner that is both medically appropriate and in compliance with applicable state and federal laws and regulations. The appropriate management of pain, particularly as related to the prescribing of opioid analgesics may include the following:

- **Adequate attention to initial assessment to determine if opioids are clinically indicated and to determine risks associated with their use in a particular individual with pain:** Not unlike many drugs used in medicine today, there are significant risks associated with opioids and therefore benefits must outweigh the risks.
- **Adequate monitoring during the use of potentially abusable medications:** Opioids may be associated with substance use disorder and other dysfunctional behavioral problems, and some patients may benefit from opioid dose reductions or tapering or weaning off the opioid.
- **Adequate attention to patient education and informed consent:** The decision to begin opioid therapy for chronic pain is a shared decision of the clinician and patient after a discussion of the risks and a clear understanding that the clinical basis for the use of these medications for chronic pain is limited, that some pain may worsen with opioids, and taking opioids with other substances (such as benzodiazepines, alcohol, cannabis, or other central nervous system depressants) or certain conditions (e.g., sleep apnea, mental illness, pre-existing substance use disorder) may increase risk.
- **Justified dose escalation with adequate attention to risks or alternative treatments:** Risks associated with opioids increase with escalating doses as well as in the setting of other comorbidities (i.e. mental illness, respiratory disorders, pre-existing substance use disorder and sleep apnea) and with concurrent use with respiratory depressants such as benzodiazepines or alcohol.
- **Avoid excessive reliance on opioids, particularly high dose opioids for chronic pain management:** It is strongly recommended that prescribers be prepared for risk

management with opioids in advance of prescribing, and should use opioid therapy for chronic pain that is not cancer-related, or part of palliative care or end-of-life care, only when non-opioid and non-pharmacological options have not been effective. Maintain opioid dosage as low as possible and continue only if clear and objective outcomes are being met.

- **Utilization of available tools for risk mitigations:** The state prescription drug monitoring program should be checked in advance of prescribing opioids and should be utilized for ongoing monitoring.

## GUIDELINES FOR THE CHRONIC USE OF OPIOID ANALGESICS

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**WORKGROUP ON FSMB'S MODEL POLICY ON THE USE OF OPIOID ANALGESICS IN THE TREATMENT OF CHRONIC PAIN**

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FSMB Immediate Past Chair

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Georgetown University School of Medicine

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Washington State Medical Quality  
Assurance Commission

Elizabeth Kilgore, MD  
Food and Drug Administration (FDA)

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American Osteopathic Association (AOA)

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Case Western Reserve University School  
of Medicine

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American Medical Association (AMA)

Joel B. Rose, DO  
Florida Board of Osteopathic Medicine

Angela Carol, MD, CCFP, FCFP  
College of Physicians & Surgeons of Ontario

George "Buddy" C. Smith, Jr., MD  
Alabama Board of Medical Examiners

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American Society of Addiction Medicine (ASAM)

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Paul R. DeRensis, JD  
Massachusetts Board of Registration in Medicine

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Pennsylvania State Board of Medicine

# Exhibit “B”

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**Education/Training**

**University of Washington School of Medicine, Seattle, WA**  
Pain Medicine Fellowship, 07/95-06/96  
Anesthesiology Residency, 07/92-06/95  
Doctor of Medicine, 08/87-06/91  
Wood Library-Museum Fellow in the History of Medicine, 11/95

**Deaconess Medical Center, Spokane, WA**  
Family Practice Transitional Internship, 07/91-06/92

**University of Idaho, Moscow, ID**  
B.S. Vertebrate Zoology, 08/84-05/87  
*Summa cum laude*  
Alumni Award for Excellence  
Coach, Moscow High School Debate Team

**Liberty Baptist College, Lynchburg, VA**  
Biology Major, 08/83-06/84  
Intercollegiate Debate Team  
Chancellor's Scholarship

**Boyd School of Law, University of Nevada, Las Vegas, NV**  
Juris Doctor, 08/05-06/08,  
Society of Advocates Moot Court Team,  
Finalist, American Bar Association Western Regional Negotiation  
Competition  
CALI Awards for Excellence: (class high exam scores)  
Evidence, Professional Responsibility  
Family Law, Workers Compensation

**Seton Hill University, Greensburg, Pennsylvania**  
MFA Candidate, 2021-2023

**Current Medical Licensure**

Nevada  
Washington (Inactive)  
Colorado  
Idaho  
Wisconsin  
Alabama  
Texas  
Mississippi

**Current Legal Licensure**

Nevada

**Medical Work History**

**01/16 to Present: Flamingo Medical Clinic**  
Medical Director/ Primary Care/ Pain Management/  
Addiction Medicine/ PreP Clinic

**10/15 to 01/16: Integrated Pain Specialists**  
Staff Physician

**03/14 to 10/15: Urgent Care Extra, LLC, Las Vegas, NV**  
Staff Physician, Primary Care/ Urgent Care/ All Ages

**11/11 to 09/12: Colorado Anesthesia Associates/  
Vail Valley Medical Center, Vail, CO**  
Staff Physician/ Anesthesiology and Pain Management

**09/08 to 11/11: University of Washington School of Medicine/  
VA Puget Sound Health Care System, Seattle, WA**  
Physician Risk Manager, 2009- 2011  
Faculty Anesthesiologist, 2009- 2011  
Staff Anesthesiologist, 2008- 2009

**12/99 to 09/08: Summit Anesthesia Consultants, Inc., Las Vegas, NV**  
Shareholder Anesthesiologist, 2001- 2008  
Staff Anesthesiologist, 1999- 2001

**07/96 to 12/99: Associated Anesthesiologists of Reno, Inc., Reno, NV**  
Partner Anesthesiologist, 1998- 1999  
Staff Anesthesiologist, 1996- 1999

**Board Certification/ Fellow Status/ Professional Qualifications**

Fellow, American College of Legal Medicine, 2010- present  
Diplomate, American Board of Anesthesiology, 1998-present  
Diplomate, National Board of Medical Examiners, 1992-present  
Buprenorphine-Qualified Physician Pursuant to DATA 2000, 2016-present

**Former Professional Appointments**

Reviewer, American Society of Anesthesiologists Closed Claims Project  
Member, Committee on Professionalism, UW Department of Anesthesiology  
Member, University of Washington School of Medicine Admissions Committee  
Member, VAPSHCS Protected Peer Review Committee  
Member, VAPSHCS Clinical Executive Credentialing and Privileging Board  
Member, VAPSHCS Patient Safety Committee

**Previous and Current Professional Memberships**

International Association for the Study of Pain  
American Academy of Pain Medicine  
American College of Legal Medicine  
American Association for Justice  
Nevada Justice Association  
American Society of Anesthesiologists  
American Society of Regional Anesthesia  
Clark County Medical Society  
Nevada State Medical Association  
Nevada State Society of Anesthesiologists  
Washington State Society of Anesthesiologists

**Current and Former Special State and National Responsibilities**

Member, Board of Scientific Advisors, American Council on Science and Health,  
November 2019-present

Member, Medical Advisory Board, Dreamsickle Kids Foundation,  
(Pediatric Sickle Cell Disease Foundation)  
November 2019-present

Member, State Bar of Nevada Fee Dispute Committee, 2020-present

University of Washington School of Medicine Alumni Advisory Board/ Medical  
School Class (1991) Representative, 2010-present

Chair, Board of Directors, American Society of Anesthesiologists Political  
Action Committee (ASAPAC), 2004-2006



Member, Board of Directors, American Society of Anesthesiologists Political Action Committee (ASAPAC), 2000-2004

Delegate, House of Delegates, American Society of Anesthesiologists, 2002-2006

Member, Governmental Affairs Committee, American Society of Anesthesiologists, 2000-2006

Member, Committee on Affiliate Membership, American Society of Anesthesiologists, 2002-2003

President, Nevada State Society of Anesthesiologists, 2002-2004

**Book Chapters & Abstracts:**

Laird, D, et al. Pain management and opioids. In: Quang T (ed). Understanding the principles and practice of legal oncology. New York: McGraw Hill, 2022.

Darnall, BD, Laird, D, et al., International Stakeholder Community of Pain Experts and Leaders Call for an Urgent Action on Forced Opioid Tapering. Pain Med. 2019 Mar 1;20(3):429-433.

Laird, D. Use of Continuous End-Tidal Carbon Dioxide Tracing to Establish Pre-Hospital Esophageal Intubation as the Cause of Death in a Young Asthmatic Woman. Abstract and Poster, American College of Legal Medicine, Las Vegas, NV, February 2017

Laird, D. False Expert Testimony in a Medical Negligence Case. Abstract and Poster, American College of Legal Medicine, Las Vegas, NV, February 2017

Laird, D. Optical Forensic Examination of Questioned Medical Record Documents. Abstract and Poster, American College of Legal Medicine, Austin, TX, February 2016

Laird, D. A lack of standards, the reporting of VA providers to the National Practitioner Data Bank. Abstract and Poster, American College of Legal Medicine, Las Vegas, NV, February 2011

Ready LB, Laird D. The interface between acute and chronic pain. In: Ashburn MA (ed). The management of pain. London: Churchill Livingstone, 1998.

# Exhibit

## “C”



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Medical Records Review/ Report \$300.00/ hour

**Deposition Testimony**

(Two-hour minimum received 10 business days in advance) \$650.00/ hour

**Trial Testimony**

(Four hour minimum received 10 business days in advance,  
travel costs paid 14 business days in advance) \$650.00/ hour

**Deposition and Trial Testimony Previous Four Years**

Dillard v. Harko, LLC d/b/a Harbor Island Apartments, et al.	Nevada
Romans v. Presbyterian Healthcare Services Deposition	New Mexico
Marty v. Malin Deposition, Trial	Nevada
Regidor v. Pacificare Deposition	Nevada
Roth v. Zalik Deposition	Illinois
Jones v. Southern Hills Hospital Deposition	Nevada
Hernandez Mendez v. Loper Enterprises Deposition	Nevada
Martinez v. Silver et al. Deposition	Nevada
Mesa v. Schindler Elevator, Inc., et al.	Nevada
Murdock v. Duncan Attwood, et al.	Nevada
Johnson v. Villagran	Nevada
Goldklang v. Toia	Nevada
Sinohui v. ATS Specialized	Nevada